

It For the control o caterpillars on Ve tables, Silvaculture and food crops (i.e. soyheans, peanus, potatoes, etc.)

## B A T S (Biotech Action Tracking System)

*	Action Type Registroher - Fast Track
•	Company Number 58788
	Registration Name (Case No.) 58788-3
٠	company Name ChOP Genetics International
	Product Name GUSANO-BIOLOGICAL Pesticide
	Chemical Name autographa californica
	EPA Recv'd Date 1-26-93
**	Pesticide Type Microbial - Virus
	Statutory Date
	Action Code 160
	PM Team
	contact/Reviewer Linda a. Hollis
	Federal Register Date
	Review Status Registered
	Tolerance/Exemptions Exempt From the heavement of a Toleran
	Date Logged Out 3/25/94
	EPAAction 17 Unconditional Rogistration

A = Amendment

F = Fast Track

N = Non Fast Track

s = sln

E = EUP

X = Notification

\*\* Fungicide/Herbicide, Insecticide, Biological, Microbial (GEMP, Indigenous/Nonindigenous), Biochemical, Transgenic Plant

#### Reference Files System

#### Product Data Report

Identification Number: 70051-43 Case Barcode: 048926

Product Name: GUSANO BIOLOGICAL PESTICIDE

Case Type: R Federal Registration

Company: 70051 THERMO TRILOGY CORP

Product Manager: 92 Phil Hutton Product Status: C Cancelled

Cancel/Transfer Reason: 32 Maint. Fee Non-Payment - Registrant Req.

Formulation Code: 06 Wettable Powder

Toxicity Category: 3 Caution RCRA Classification: Not Available

Label Date: 94/03

Orig Prod Approval Date: 03/25/94

Approval Date: 06/12/97 Cancellation Date: 07/21/98 Stocks Date: 01/15/99

Transferred: No Suspended: No

Use Categories Pest Categories

Terrestrial Food Crop: Non-Pest: No No Terrestrial Feed Crop: Disinfectant: No No Terrestrial Non-Food Crop: Fungal: No No Invertebrate: Aquatic Food Crop: No No Aquatic Non-Food Outdoor: No Nematodal: No Aquatic Non-Food Residential: No Plant: No Aquatic Non-Food Industrial: Vertebrate: No No

Greenhouse Food Crop: No

Greenhouse Non-Food Crop: No Miscellaneous Flags Forestry: No ------

Residential Outdoor: No

Indoor Food: No Restricted Use: No Indoor Non-Food: No Conditional Use: No

Indoor Residential: No Reregistration: No Indoor Medical: No Child Resistant Packaging: No

Special Review: No



WASHINGTON, D.C. 20460

MAR - 8 1994

#### **MEMORANDUM**

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SUBJECT:

Consideration of an Unconditional Registration for the

New Active Ingredient Polyhedral Occlusion Bodies of

the nuclear polyhedrosis virus of Autographa

californica (AcMNPV) for the control of caterpillars on

vegetable, field and silvaculture crops. EPA File

Symbol 587/88-6/

FROM:

Stephen Johnson, Acting Director

Registration Davision

TO:

Douglas D. Campt, Director Office of Pesticide Programs

#### ISSUE

Should an unconditional registration for the subject product which contains the new active ingredient polyhedral occlusion bodies of the nuclear polyhedrosis virus of <u>Autographa californica</u> be granted under FIFRA Section 3(c)(5).

#### BACKGROUND

#### Regulatory History

On April 24, 1991, the Registration Division of the Office of Pesticide Programs received an application for the registration of Gusano from Espro, Inc., (subsequently acquired by Crop Genetics International of Columbia, Maryland). A Federal Register Notice of the availability of the application for registration of a new active ingredient and a request for comment was published on May 1, 1992 (Vol. 57 No. 85, pp. 18876). comments regarding this submission were received. application was for Autographa californica NPV (trade name Gusano), an insect-virus based product containing the polyhedral occlusion bodies of the multiple-embedded nuclear polyhedrosis virus of Autographa californica (AcMNPV). This product shall be used for the control of caterpillars (over 30 insect species infected) on Vegetable, Field and Silvaculture Crops. applicant has submitted a request for a permanent exemption from the requirement of a tolerance on all Raw Agricultural Commodities for Autographa californica (AcMNPV) (Pet.

No. F4089).

#### Recommended Uses and Application Timing

Gusano is an end-use product which is produced in the living larvae of <u>Trichoplusia</u> <u>ni</u> (cabbage looper). The active ingredient consists of polyhedral occlusion bodies of <u>Autographa californica</u> (AcMNPV) plus insect components/body parts of <u>T. ni</u>. as the inert. Conversely, both the active and inert ingredients are produced contemporaneously during in vivo production of the polyhedra in living insects and are identical to the technical grade material.

Gusano is to be used on vegetable and field crops as well as on trees of various species. Label directions for this product indicate that applications should be made when larvae are in the first and second instar, and are actively feeding on foliage. This product should be applied before extensive foliar damage has occurred. Larvae must ingest the polyhedra in order to become infected, this is attained via consummation of the sprayed plant material. Gusano will be packaged as a lyophilized powder to be tank mixed with water.

#### Satisfaction of Data Requirements

#### TOXICOLOGY DATA

The toxicological data considered in support of this registration include a: Acute Oral Toxicity/Pathogenicity; Acute Pulmonary Toxicity in the rat; Acute Dermal Toxicity in the rabbit; Acute Intravenous Toxicity; Primary Eye Irritation Study in the rabbit; Hypersensitivity Study; and a Cell Culture Study. Based on existing data available from the open literature, the Science Analysis and Coordination Branch (SACB) recommends that the information submitted are sufficient to support the waiver requests. Data waivers have been requested and granted for these studies.

#### PRODUCT IDENTITY/CHEMISTRY

These studies have been submitted and found acceptable.

#### MANUFACTURING PROCESS

These studies have been submitted and found acceptable.

#### DISCUSSION OF FORMATION OF UNINTENTIONAL INGREDIENTS

These studies have been submitted and found acceptable.

#### ANALYSIS OF SAMPLES

These studies have been submitted and found acceptable.

#### CERTIFICATION OF INGREDIENT LIMITS

These studies have been submitted and found acceptable.

#### ECOLOGICAL EFFECTS DATA

Data waivers for the ecological effects data considered in support of this product have been requested and granted for the following studies:

#### Avian Studies

No adverse effects to birds are expected from the use of this product.

#### Fish Studies

No data on the effect of <u>Autographa</u> NPVs on fish have been reported in the open literature. However, reports in the literature which tested NPVs other than <u>Autographa</u> indicate that NPV's do not cause adverse effects to fish.

#### Mammalian Wildlife

These studies are required only when toxicology data are inadequate for assessment of hazard to wild mammals. The available toxicology data indicates that risk to wild mammals from the proposed uses of <u>Autographa californica</u> insecticide is minimal.

#### Aquatic Invertebrate Studies

No adverse effects to aquatic invertebrates are expected from the use of this product.

#### Estuarine and Marine Animal Studies

No adverse effects to estuarine and marine animals are expected from the use of this product.

#### Nontarget Plant Studies

No nontarget plant hazard is expected from the use of this product.

#### Honey Bee Studies

No adverse effects to honey bees are expected from the use of this product.

#### Nontarget Beneficial Insect Studies

No adverse effects to predatory or beneficial insects are expected from the use of this product.

#### Endangered Species Considerations

This product may be expected to be used throughout the United States with possible exposure to all endangered/threatened species that are susceptible to this virus. However, based on the toxicity and exposure data, the Ecological Effects Branch feels that there will not be a "may affect" situation for endangered mammals, birds, non-lepidopteran invertebrates, plants and aquatic species.

The use of this product may however affect endangered lepidopteran insect species in Washington, Oregon, California and Florida. However, the Agency at this time does not require a labeling statement regarding Endangered Lepidopteran Species.

#### DIETARY EXPOSURE DATA

Dietary exposure data is required only if the submitted studies indicate that Tier II or III Toxicology data are required. As such, these data were not required.

#### ENVIRONMENTAL FATE DATA

Environmental assessments are not required for this product unless a risk assessment has been requested. The human and nontarget animal toxicity studies indicate that the proposed product is of a low risk therefore, these data are not required.

#### Recommendation

The Registration Division recommends that the subject product, containing Polyhedral Occlusion Bodies of the nuclear polyhedrosis virus of <u>Autographa californica</u> (AcMNPV) be registered under FIFRA Section 3(c)(5).

Concur:	Dat 824	<b></b>
Nonconcur:		
Comments:		
Deter	MAR - 9 1994	

#### ATTACHMENTS:

Fact Sheet

Tolerance Document (under separate cover) Scientific Reviews (HED & EFED)

#### NOTE TO REVIEWERS

There are no end-use product acute studies submitted for this product. This is because the product formulation consists only of ingredients qualifying as unlikely to pose human health risks as per the revised Section 158 data requirements (insect parts). Therefore, as per these requirements, toxicity categories and precautionary labeling are based upon the data for the TGAI, and data on the end-use product are waived.

Phil Hutton

MAR - 8 1994

#### **MEMORANDUM**

Consideration of an Unconditional Registration for the SUBJECT:

New Active Ingredient Polyhedral Occlusion Bodies of

the nuclear polyhedrosis virus of Autographa

californica (AcMNPV) for the control of caterpillars on

vegetable, field and silvaculture crops. EPA File

Symbol 58788-G.

FROM:

Stephen Johnson, Acting Director

Registration Division

TO:

Douglas D. Campt, Director Office of Pesticide Programs

#### **ISSUE**

Should an unconditional registration for the subject product which contains the new active ingredient polyhedral occlusion bodies of the nuclear polyhedrosis virus of Autographa californica be granted under FIFRA Section 3(c)(5).

#### BACKGROUND

#### Regulatory History

On April 24, 1991, the Registration Division of the Office of Pesticide Programs received an application for the registration of Gusano from Espro, Inc., (subsequently acquired by Crop Genetics International of Columbia, Maryland). A Federal Register Notice of the availability of the application for registration of a new active ingredient and a request for comment was published on May 1, 1992 (Vol. 57 No. 85, pp. 18876). comments regarding this submission were received. application was for Autographa californica NPV (trade name Gusano), an insect-virus based product containing the polyhedral occlusion bodies of the multiple-embedded nuclear polyhedrosis virus of Autographa californica (AcMNPV). This product shall be used for the control of caterpillars (over 30 insect species infected) on Vegetable, Field and Silvaculture Crops. applicant has submitted a request for a permanent exemption from

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DATE	2/24/94	2/24/94	3-7-91	f				4.0
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No. F4089).

#### Recommended Uses and Application Timing

Gusano is an end-use product which is produced in the living larvae of <u>Trichoplusia</u> <u>ni</u> (cabbage looper). The active ingredient consists of polyhedral occlusion bodies of <u>Autographa californica</u> (AcMNPV) plus insect components/body parts of <u>T. ni</u>. as the inert. Conversely, both the active and inert ingredients are produced contemporaneously during in vivo production of the polyhedra in living insects and are identical to the technical grade material.

Gusano is to be used on vegetable and field crops as well as on trees of various species. Label directions for this product indicate that applications should be made when larvae are in the first and second instar, and are actively feeding on foliage. This product should be applied before extensive foliar damage has occurred. Larvae must ingest the polyhedra in order to become infected, this is attained via consummation of the sprayed plant material. Gusano will be packaged as a lyophilized powder to be tank mixed with water.

#### Satisfaction of Data Requirements

#### TOXICOLOGY DATA

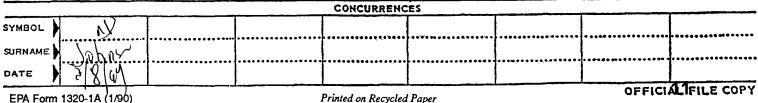
The toxicological data considered in support of this registration include a: Acute Oral Toxicity/Pathogenicity; Acute Pulmonary Toxicity in the rat; Acute Dermal Toxicity in the rabbit; Acute Intravenous Toxicity; Primary Eye Irritation Study in the rabbit; Hypersensitivity Study; and a Cell Culture Study. Based on existing data available from the open literature, the Science Analysis and Coordination Branch (SACB) recommends that the information submitted are sufficient to support the waiver requests. Data waivers have been requested and granted for these studies.

#### PRODUCT IDENTITY/CHEMISTRY

These studies have been submitted and found acceptable.

#### MANUFACTURING PROCESS

These studies have been submitted and found acceptable.



on Recycled Paper

\*U.S. Government Printing Office: 1992 --- 620-856/40672

#### **DISCUSSION OF FORMATION OF UNINTENTIONAL INGREDIENTS**

These studies have been submitted and found acceptable.

#### ANALYSIS OF SAMPLES

These studies have been submitted and found acceptable.

#### CERTIFICATION OF INGREDIENT LIMITS

These studies have been submitted and found acceptable.

#### ECOLOGICAL EFFECTS DATA

Data waivers for the ecological effects data considered in support of this product have been requested and granted for the following studies:

#### Avian Studies

No adverse effects to birds are expected from the use of this product.

#### Fish Studies

No data on the effect of Autographa NPVs on fish have been reported in the open literature. However, reports in the literature which tested NPVs other than Autographa indicate that NPV's do not cause adverse effects to fish.

#### Mammalian Wildlife

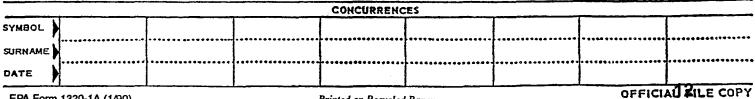
These studies are required only when toxicology data are inadequate for assessment of hazard to wild mammals. available toxicology data indicates that risk to wild mammals from the proposed uses of Autographa californica insecticide is minimal.

#### Aquatic Invertebrate Studies

No adverse effects to aquatic invertebrates are expected from the use of this product.

#### Estuarine and Marine Animal Studies

No adverse effects to estuarine and marine animals are expected from the use of this product.



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#### Nontarget Plant Studies

No nontarget plant hazard is expected from the use of this product.

#### Honey Bee Studies

No adverse effects to honey bees are expected from the use of this product.

#### Nontarget Beneficial Insect Studies

No adverse effects to predatory or beneficial insects are expected from the use of this product.

#### Endangered Species Considerations

This product may be expected to be used throughout the United States with possible exposure to all endangered/threatened species that are susceptible to this virus. However, based on the toxicity and exposure data, the Ecological Effects Branch feels that there will not be a "may affect" situation for endangered mammals, birds, non-lepidopteran invertebrates, plants and aquatic species.

The use of this product may however affect endangered lepidopteran insect species in Washington, Oregon, California and Florida. However, the Agency at this time does not require a labeling statement regarding Endangered Lepidopteran Species.

#### DIETARY EXPOSURE DATA

Dietary exposure data is required only if the submitted studies indicate that Tier II or III Toxicology data are required. As such, these data were not required.

#### ENVIRONMENTAL FATE DATA

Environmental assessments are not required for this product unless a risk assessment has been requested. The human and nontarget animal toxicity studies indicate that the proposed product is of a low risk therefore, these data are not required.

#### Recommendation

The Registration Division recommends that the subject product, containing Polyhedral Occlusion Bodies of the nuclear polyhedrosis virus of Autographareactifornica (AcMNPV) be symbol registered under FIFRA Section 3(c)(5).

SURNAME DATE

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Concur:	Pour A Cu	
Nonconcur:	No.	•
Comments:		
Date:	MAR - 9 1994	
ATTACHMENT	rs: Fact Sheet	

Tolerance Document (under separate cover) Scientific Reviews (HED & EFED)

CONCURRENCES							
SYMBOL					4444		
SURNAME							
DATE				••••••••••••	••••••		
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EPA Form 1320-1A (1/90)

## **SEPA**

# Pesticide Fact Sheet

Name of Chemical: Polyhedral Occlusion Bodies of the nuclear polyhedrosis virus of Autographa californica

Reason for Issuance: Unconditional Registration of a New Microbial

Pesticide

Date Issued: March 18, 1994

Fact Sheet Number:

#### 1. <u>Description of Microbial Pesticide</u>: Virus

Generic Name(s): Polyhedral occlusion bodies of the nuclear polyhedrosis virus of <u>Autographa californica</u>

Trade Name: GUSANO

EPA/OPP Pesticide Chemical Code: 128885

Year of Initial Registration: 1994

Pesticide Type: Insecticide

U.S. and Foreign Producers: Crop Genetics International

10150 Old Columbia Road

Columbia, Maryland 21046-1704

#### 2. <u>Use Patterns</u> and Formulations

Application Site: Vegetables: tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli and onion. Field Crops: cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweet potatoes, tobacco, sunflower and sugarbeets. Silvaculture: trees of various species.

Application Rates: application is to be qt the rate of 5-50 gams/acre or 100-500 billion occulusion bodies/acre. Application should be made when larvae are in the first and second instar. Larvae must ingest polyhedra to be infected.

Pests Controlled: alfalfa looper, beet armyworm, black cutworm, bollworm, cabbage looper, celery looper, corn earworm, cotton leafperforator, diamondback moth, douglass fir tussock moth, eastern tent caterpillar, elm spanworm, european imported cabbageworm, orangestriped oakworm, pink bollworm, saltmarsh caterpillar, southwestern corn borer, soybean looper, tobacco budworm, tomato fruitworm, white cutworm.

#### 3. Science Findings

The available information that has been reviewed suggests that <u>Autographa californica</u> nuclear polyhedrosis virus is potentially safer than many conventional pesticides currently used for control of the same pest.

#### Microbial Pesticide Characteristics

<u>Autographa californica</u>, the alfalfa looper, is a naturallyoccuring microbial pest which displays a broad host range, infecting over 30 insect species.

Nuclear polyhedrosis viruses (NPV), classified in the family <a href="Baculoviridae">Baculoviridae</a>, are structurally large and complex DNA-containing viruses infecting insects. The active ingredient in GUSANO is the multiple-embedded nuclear polyhedrosis virus of <a href="Autographa californica">Autographa californica</a> (AcMNPV), alfalfa looper.

#### Mode of Action

After ingestion of the virus the occlusion body protein, called polyhedrin, is solubilized by the alkaline conditions of the larval midgut causing the liberation of infections virions or nucleocapsids from the polyhedral inclusion body (PIB). The nucleocapsids attached to the midgut epithelial cells, are transported through the cytoplasm to the nucleus, followed by uncoating of the viral genome and initiation of viral replication. During replication NPVs produce either a single nucleocapsid per envelope (SNPV) or, as is the case with the NPV of <u>Autographa californica</u> one to many nucleocapsids per envelope (MNPV) which are occluded in polyhedrin. As the disease progresses infected cells lyse, normal physiological processes are disrupted, the target insect becomes sluggish with the integument rupturing causing death.

#### DISCUSSION OF DATA REQUIREMENTS

#### TOXICOLOGY DATA

Data waivers were submitted for these studies and found acceptable.

Acute Oral/Toxicity/Pathogenicity

Acute Pulmonary Toxicity

Acute Dermal Toxicity

Acute Intravenous Toxicity

Primary Eye Irritation Study

Cell Culture Study

Hypersensitivity Study - If observed, any incidents of hypersensitivity should be reported to the Agency

#### PRODUCT IDENTITY/CHEMISTRY

Submitted and accepted

#### ECOLOGICAL EFFECTS DATA REQUIREMENTS

Requests for waivers for all Ecological Effects data requirements demonstrated that no significant risk to nontarget wildlife should be expected from exposure of this product at the proposed use rates.

#### <u>Avian Studies</u>

No adverse effects to birds are expected from the use of this product.

#### Fish Studies

Reports in the literature which tested NPVs other than  $\underline{A}$ . californica indicate that NPVs do not cause adverse effects to fish.

#### Mammalian Wildlife

These studies are required only when toxicology data are inadequate for assessment of hazard to wild mammals. The available toxicology data indicates that risk to wild mammals from the proposed uses of GUSANO insecticide is minimal.

#### Aquatic Invertebrate Studies

No adverse effects to aquatic invertebrates are expected from the use of this product.

#### Estuarine and Marine Animal Studies

No adverse effects to estuarine and marine animals are expected from the use of this product.

#### Nontarget Plant Studies

No nontarget plant hazard is expected from the use of this product.

#### Honey Bee Studies

No adverse effects to honey bees are expected from the use of this product.

#### Nontarget Beneficial Insect Studies

No adverse effects to predatory or beneficial insects are expected from the use of this product.

#### RESIDUE CHEMISTRY DATA

Residue Chemistry Data is required only if the submitted studies indicate that Tier II or III Toxicology data are required. As such, these data were not required.

#### **DIETARY EXPOSURE DATA**

Dietary exposure data is required only if the submitted studies indicate that Tier II or III Toxicology data are required. As such, these data were not required.

#### ENVIRONMENTAL FATE DATA

Environmental assessments are not required for this product unless a risk assessment has been requested. The human and nontarget animal toxicity studies indicate that the proposed product is of a low risk therefore, these data are not required.

#### Endangered Species Considerations

This product may be expected to be used throughout the United States with possible exposure to all endangered/threatened species that are susceptible to this virus. However, based on the toxicity and exposure data, the Ecological Effects Branch feels that there will not be a "may affect" situation for endangered mammals, birds, non-lepidopteran invertebrates, plants and aquatic species.

The use of this product may however affect endangered lepidopteran insect species in Washington, Oregon, California and Florida. A change in the labeling regarding Endangered Lepidopteran Species whereby a statement must be placed on the

label advising reference to the County Bulletin will be required in the future.

#### TOLERANCE ASSESSMENTS

An exemption from the requirement of a tolerance for residues of the microbial pest control agent polyhedral occlusion bodies of <u>Autographa californica</u> NPV in or on all raw agricultural commodities has been established.

#### 4. Contact person at EPA

Phillip Hutton
Product Manager 18
Registration Division
Insecticide/Rodenticide Branch
Office of Pesticide Programs
Environmental Protection Agency
401 M Street SW
Washington, DC 20460

DISCLAIMER: The information in this Pesticide Fact Sheet is a summary only and is not be used to satisfy data requirements for pesticide registration and reregistration. The complete Registration Standard for the pesticide (if available) my be obtained from the National Technical Information Service. Contact the Product Manager listed above for further information.



WASHINGTON, D.C. 20460

NOV 19 1993

**MEMORANDUM** 

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SUBJECT:

SAB Consideration of a Petition Requesting an Exemption from the Requirement of a Tolerance for <u>Autographa californica</u> nuclear polyhedrosis virus (DP Barcode D1067074 Cubricaion No. 24524044 T. D. No. 2504000)

D196797; Submission No.: S453494; I.D. No. 2F04089)

TO:

Linda Hollis/Phil Hutton (PM-018) Insecticide-Rodenticide Branch Registration Division (7505C)

FROM:

J. Thomas McClintock, Ph.D., Microbiologist

Biological Pesticide Section

Science Analysis Branch

Health Effects Division (7509C)

THROUGH:

Roy D. Sjoblad, Ph.D., Section Head

Biological Pesticide Section

Science Analysis Branch

Health Effects Division (7509C)

ACTION REQUESTED: Crop Genetics International, Inc. has submitted a request for an exemption from the requirement of a tolerance for Autographa californica nuclear polyhedrosis virus (AcNPV), the active ingredient in GUSANO. SAB received the petition for a tolerance exemption on November 19, 1993.

CONCLUSION: All product identity/characterization and mammalian toxicology data have been submitted and adequately satisfy the requirements as set forth in 40 CFR 158.740. Due to the complete lack of toxicity, pathogenicity and/or infectivity as demonstrated in the mammalian toxicology data base and based on the evaluation of all available data and other relevant information on AcNPV, SAB would recommend an exemption from the requirement of a tolerance.



WASHINGTON, D.C. 20460

NOV 1.6 1993

MEMORANDUM

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: SAB Review of Supplemental Information Submitted to

Support the Registration of GUSANO

TO:

Linda Hollis/Phil Hutton (PM-018) Insecticide-Rodenticide Branch Registration Division (7505C)

FROM:

J. Thomas McClintock, Ph.D., Microbiologist

Biological Pesticide Section

Science Analysis Branch

Health Effects Division (7509C)

THROUGH:

ACTION REQUESTED:

Roy D. Sjoblad, Ph.D., Section Head

Biological Pesticide Section

Science Analysis Branch

Health Effects Division (7509C)

Crop Genetics International, Inc. previously submitted supplemental product identity/chemistry data to support the registration of GUSANO, an insecticide containing Autographa californica nuclear polyhedrosis virus (AcNPV) as the active ingredient. During the review the Science Analysis Branch (SAB) of the Health Effects Division (HED) noted two deficiencies: verification that the original PstI restriction profile of the ACNPV isolate was, in fact, the same isolate that CGI intends to use for registration and 2) data on the detection of possible

production control procedures (see May 6, 1993 memorandum from C. Schaffer to L. Hollis/P. Hutton).

In response to a letter sent by the Agency dated July 28, 1993, CGI submitted information (September, 3, 1993) to SAB and the Registration Division addressing each of these deficiencies. has summarized CGI's response below.

contaminants in the final product; specifically, a description of

1). <u>Verification</u> that the <u>original</u> (see November 12, DISCUSSION: 1992 memorandum from J. T. McClintock to L. Hollis/P. Hutton) PstI restriction profile of the AcNPV isolate was, in fact, the same isolate that CGI intends to use for registration.

"The isolate used in the restriction CGI's Response: endonuclease (REN) pattern that were submitted with the January 22, 1993 submission is identical to the isolate that will be used in production of AcMNPV and...registration." SAB NEVER questioned the source of the AcNPV DNA used to generate the REN profiles in the January 22, 1993 submission. SAB was requesting identity of the AcNPV isolate and source of viral DNA used in the <u>ORIGINAL</u> restriction profiles submitted (i.e. AcNPV was compared to several restriction digests of <u>Spodoptera exigua</u> NPV DNA). Based on CGI's latest response, the data submitted in the original submission <u>WILL NOT</u> be used to support the registration of GUSANO. Instead, the data from the January 22, 1993 submission <u>WILL</u> be used to fulfill this data deficiency.

2). Data on the detection of possible contaminants in the final product; specifically, a description of production control procedures.

CGI's Response: CGI intends to use the same production control procedures as set forth in the Cyd-X submission of April 1, 1993 (MRID No. 427218-02).

<u>CONCLUSION</u>: All deficiencies previously noted by SAB have been adequately addressed. All data requirements for HED have been satisfied.

<sup>\*</sup>Manufacturing process information may be entitled to confidential treatment\*

#### August 26, 1993

Phillip Hutton (H7507C) USEPA Office of Pesticide Programs 401 M Street, S.W. Washington, D.C. 20460

Re: GUSANO, EPA File Symbol 58788-G (previously 58971-G)
Response to your letter of July 28, 1993

Dear Mr. Hutton:

This letter is in response to your letter of July 28, 1993, in which you raised two questions concerning Crop Genetics International's resubmission of January 22, 1993.

- 1. The isolate used in the restriction endonuclease (REN) patterns that were submitted with the January 22, 1993 submission is identical to the isolate that will be used in production of AcMNPV and is the isolate intended for registration.
- 2. With regard to the detection of possible contaminants in the final product, Crop Genetics intends to use the same production control procedures set forth in our recont Cyd-X submission of April 1, 1993.

The protocols for these procedures were submitted in our Cyd-X resubmission of April 1, 1993. See MRID No: 427218-02. These tests will be performed in lieu of the seven bacterial tests originally submitted with the Gusano submission.

If you have any questions concerning this submission, please do not hesitate to contact me.

Sincorely,

James H. Davis Vide President of Research and Devolopment

\*Manufacturing process information may be entitled to confidential treatment\*



WASHINGTON, D.C. 20460

#### MEMORANDUM

### **5** MAY 1993

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Subject: SAB Review of Supplemental Product Identity/Chemistry

Data from Crop Genetics International Corporation to Support the Registration of <u>Autographa californica</u> Nuclear Polyhedrosis Virus (Submission No.: S434992; ID

No.: 058971-G; DP Barcode No.: D188661).

To: Phillip Hutton/ Linda Hollis (PM 18)

Insecticide-Rodenticide Branch Registration Division (H7505C)

From: Cindy Schaffer, Microbiologist ( Schaffer

Biological Pesticides Section

Science Analysis Branch

Health Effects Division (H7509C)

Through: Roy Sjoblad, Ph.D., Acting Section Head

Biological Pesticides Section

Science Analysis Branch

Health Effects Division (H7509C)

Action: SAB has been asked to review supplemental product

analysis/chemistry data submitted in support of the registration by Crop Genetics International Corporation (CGI) for Gusano, an insecticide containing <u>Autographica</u> californica nuclear polyhedrosis virus (NPV) as the

active ingredient.

<u>Discussion</u>: Since the original submission included only one restriction profile, (PstI) of the NPV DNA, unless CGI states otherwise, SAB is assuming that the source of DNA (i.e. virus strain) for this profile is from the same strain intended for production. Also, the following deficiencies are still outstanding for the product analysis/chemistry package: 1. Data was not provided regarding possible contaminants in the final product that would result in the death of the bioassay insects. 2. A reference which was sited, Martignoni (1978), was not submitted.

DATA EVALUATION REPORT

Reviewed by: Cindy Schaffer, Microbiologist, SAB/HED Secondary Reviewer: J. Thomas McClintock, Ph.D., Microbiologist

SAB/HED

STUDY TYPE: Product Analysis Information

MRID NO: 426408-01; 426408-02; 426408-03

TEST MATERIAL: <u>Autographica</u> californica

Nuclear Polyhedrosis

Virus

Gusano SYNONYMS: PROJECT NO: 190IVR

> Crop Genetics International, Hanover, MD SPONSOR:

TESTING FACILITY: Crop Genetics International, Hanover, MD

Restriction Endonuclease Analysis of Gusano, TITLE OF REPORT:

Autographica Californica Multiply Enveloped Nuclear Polyhedrosis Virus; Supplement to

Product Chemistry.

AUTHOR(S): Nikolai van Beek, Douglas M. Kolodny-Hirsch

STUDY COMPLETED: 22 January 1993

CONCLUSION: Since the original submission included only

one restriction profile, (PstI) of the NPV unless CGI states otherwise, SAB is assuming that the DNA source (i.e. virus strain) for this profile is from the same strain intended for production. Also, the following deficiencies are still outstanding for the product analysis /chemistry package: Data was not provided regarding possible contaminants in the final product that would result in the death of the bioassay insects. 2. A reference which was sited, Martignoni

(1978), was not submitted.

NOTE: This material contains CBI

#### PRODUCT ANALYSIS

151A-10 Product Analysis and Disclosure of Ingredients

Confidential Statement of Formula has been submitted. polyhedral occlusion bodies of the nuclear contains 3.3% polyhedrosis virus of Autographica californica as the active ingredient; and 96.7% Trichoplusia ni body parts as inerts.





<u>Unintentional Ingredients/Analytical Methods</u>:

DISCUSSION: Since the original submission included only one restriction profile, (PstI) of the NPV DNA, unless CGI states otherwise, SAB is assuming that the DNA source (i.e. virus strain) for this profile is from the same strain intended for production. Also, the following deficiencies are still outstanding for the product analysis/chemistry package:

- Data was not provided regarding possible contaminants in the final product that would result in the death of the bioassay insects.
- 2. A reference which was sited, Martignoni (1978), was not submitted.

<sup>\*</sup>Manufacturing process information may be entitled to confidential treatment\*





WASHINGTON, D.C. 20460

009848

NOV 1 2 1992

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

#### **MEMORANDUM**

SUBJECT: SAB Review of a New Product Registration Application for

GUSANO, a Baculovirus-Based Product (DP Barcode: D172020; Submission No. S407776; MRID Nos. 420730-00, -01, 419357-

02)

TO:

Linda Hollis/Phil Hutton

Insecticide-Rodenticide Branch Registration Division (H7505C)

FROM:

J. Thomas McClintock, Ph.D., Microbiologist (

Biological Pesticide Section

Science Analysis Branch

Health Effects Division (H7509C)

THROUGH:

Roy D. Sjoblad, Ph.D., Acting Section Head

Biological Pesticide Section

Science Analysis Branch

Health Effects Division (H7509C)

ACTION REQUESTED: On behalf of CGI (formerly Espro, Inc.), Jellinek, Schwartz, Connolly and Freshman, Inc. have submitted an application for the registration of GUSANO, an insect virus-based insecticidal product containing the polyhedral inclusion bodies (PIBs) of the multiple-embedded nuclear polyhedrosis virus of Autographa californica (AcMNPV), the alfalfa looper. With the exception of certain Product Chemistry studies (i.e. 151A-10 through -15, -17) waivers have been requested for the remaining portion of Series 151A and for all of the toxicology data requirements as outlined in Subdivision M of the Pesticide Assessment Guidelines.

BACKGROUND INFORMATION: Nuclear polyhedrosis viruses classified in the family <u>Baculoviridae</u>, are structurally large and complex DNA-containing viruses infecting insects. Although some NPVs display a specific host range, the NPV of A. californica displays a broad host range infecting over 30 insect species. After ingestion of the virus the occlusion body protein, called polyhedrin, is solubilized by the alkaline conditions of the larval causing the liberation of infectious virions nucleocapsids from the polyhedral inclusion body The (PIB). nucleocapsids attach to the midgut epithelial cells, transported through the cytoplasm to the nucleus, followed by

uncoating of the viral genome and initiation of viral replication. During replication NPVs produce either a single nucleocapsid per envelope (SNPV) or, as is the case with the NPV of  $\underline{A}$ . californica, one to many nucleocapsids per envelope (MNPV) which are occluded in polyhedrin. As the disease progresses infected cells lyse, normal physiological processes are disrupted, the target insect becomes sluggish with the integument rupturing causing death.

CONCLUSIONS/RECOMMENDATIONS: Summarized below is data and information required, but not limited to, for the registration of GUSANO. To fulfill the data requirements for Product Identity/Chemistry the following information and/or data must be submitted:

- Since registrant is the using a single restriction endonuclease (REN) profile to support the product identity requirements a discussion should follow regarding the expected REN patterns of AcMNPV propagated in various hosts and elaborate on any differences (host-induced modifications) which might occur. SAB is also unclear if the AcMNPV isolate used in the REN analysis is the same isolate (or active ingredient) intended for registration. If not, the registrant should provide a REN analysis of their active ingredient for comparison. If the REN profile between the AcMNPV isolates is significantly different then the acceptability of the waiver requests for the mammalian toxicology requirements would be reevaluated.
- A revised CSF stating that the product contains PIBs of the nuclear polyhedrosis virus of <u>Autographa californica</u> (alfalfa looper) as the active ingredient (see 151A-10 [b]).
- O SAB has focused on assuring lack of contamination with pathogenic toxin-producing microorganisms. Because of the <u>in vivo</u> production method the registrant must (a) specify the specific screens for the detection of significant mammalian pathogens and (b) perform an intraperitoneal injection (10 PIBs/animal) or an acute oral screen (endpoints should include signs of clinical toxicity, mortality) for each independent batch (see 151A-15).
- O Specify QA/QC procedures in place to insure a healthy or disease-free insect colony.

To support the registration of GUSANO the registrant has requested waivers for all acute toxicology requirements. The data and information submitted by the registrant are sufficient to support the waiver request for all toxicology studies since the lyophilized end-use product (EP) which consists solely of ACMNPV PIBs and S. exigua body parts is identical to the technical grade material. Consequently, SAB would not recommend further toxicity testing on the EP.

O <u>152A-15</u>. No cases or incidents of hypersensitivity to AcMNPV have been observed. The applicant <u>must</u> report any incidents of hypersensitivy to the Agency should any incident be observed in the future.

#### SUMMARY OF PRODUCT DATA/INFORMATION

The requirements for Series 151A-10, 151A-11, and 151A-16 have been partially satisfied. The data and information needed to fulfill the requirements for the remaining Series are incomplete.

<u>CLASSIFICATION</u>: Supplementary.

#### SUMMARY OF TOXICOLOGY STUDIES

157A-10. Acute Oral Toxicity/Pathogenicity. The applicant has requested a waiver for the acute oral toxicity study based, in part, on an acute oral study performed by Hazelton Laboratories (Acute Oral-Rats; Project No. 183-195 AGM; February 21, 1973) using A. californica NPV. Twenty male and 20 female rats were administered by oral intubation 4.35 x10 AcMNPV PIBs/ml and observed for a 21-day period. Several criteria (physical appearance, behavior, clinical studies, organ weights, and gross and microscopic pathology) were used to evaluate compound related effects. No differences were noted, using any of these criteria, between AcMNPV-treated animals and untreated controls.

Oral feeding studies were also performed by Rosner-Hixson Laboratories (Chicago, ILL) using PIBs from S. exiqua and S. frugiperda NPVs (Laboratory No. 1110-66; November, 11, 1966). In these studies mice were orally dosed with a 1 x 10 PIB suspension in a volume of 0.2 ml. Control animals received 0.2 ml of saline without PIBs. Body weights were recorded weekly and at the end of the two-month study the mice were sacrificed and subjected to necropsy. No differences in body weight gains or significant changes in any of the organs following necropsy were observed between treated and control group animals.

In a third oral feeding study (Carey and Harrap, 1980,  $\underline{\text{In}}$  Invertebrate Systems in Vitro) various tissue samples were collected from rats treated with  $\underline{\text{S}}$ .  $\underline{\text{littoralis}}$  and/or  $\underline{\text{S}}$ .  $\underline{\text{exempta}}$ , two closely related  $\underline{\text{Spodoptera}}$  NPVs, and examined for the presence of virus by giemsa stain. Samples were also assayed for virus by cell culture and bioassay techniques. When samples from treated rats were inoculated into cell culture certain tissues (liver) gave spurious cytopathic effects. However, further evidence failed to substantiate the presence of PIBs. Using giemsa stain, macerates of some gut tissues revealed the presence of polyhedra on Days 0-2, on Day 14 and in one instance on Day 21. These macerates were infectious when fed to  $\underline{\text{S}}$ .  $\underline{\text{littoralis}}$  larvae.

In a subacute oral study rats were continuously exposed to daily feedings of <u>Spodoptera</u> NPVs for either 45 or 90 days. Smears of tissue macerates from 4 rats (2 males and 2 females) were examined at 45 days and from the remaining rats at 90 days for the presence of polyhedra. No polyhedra were detected in the tissue smears or following cell culture challenge. However, serological testing of sera from treated animals indicated the presence of antibody to <u>Spodoptera</u> particles in a few treated animals. The significance of these observations was not discussed.

Additional data from various feeding studies using different baculoviruses was also submitted to support the registration of GUSANO. In each instance no adverse effects were reported.

<u>CLASSIFICATION</u>: Acceptable. Toxicity Category IV. The data and information submitted are sufficient to satisfy the Acute Oral Toxicity study requirement for the active ingredient.

152A-11. Acute Dermal Toxicity. The applicant has requested a waiver for the acute dermal toxicity study based on an acute dermal toxicity study using A. californica NPV (Hazelton Laboratories, 1972. Primary Skin Irritation in Rabbits, Project No. 183-195) and other NPVs as the test material. Following a single 24-hr application (2.17 x  $10^6$  PIBs/0.5 ml/treatment site) to intact and abraded skin, rabbits were observed for 72 hr and "scored" for adverse effects according to the Draize system. No dermal irritation or treatment-related toxicity was observed during the course of the study.

Additional data/information for dermal studies performed by Rosner-Hixson Laboratories (Chicago, ILL, 1967) were submitted to support the waiver request. Briefly, when applied to abraded skin of guinea pigs both freed virions and PIBs from <u>S. exigua</u>, <u>S. frugiperda</u>, <u>Heliothis zea</u>, <u>Trichoplusia ni</u>, and <u>Estigmene acrea</u> at a concentration of 10 to 10 PIBs/mg failed to produce a reaction. Other data/information was submitted which provided further evidence that NPVs do not elicit a response following topical application to the skin.

<u>CLASSIFICATION</u>: Acceptable. Toxicity Category IV. The data are adequate to satisfy the dermal toxicity and dermal irritation requirements for the EP. This study however, is not required for the technical grade active ingredient.

<u>152A-12.</u> Acute Pulmonary Toxicity. The applicant has requested a waiver for this requirement based on studies using the NPV of  $\underline{A}$ . californica as well as other NPVs as the test material. In the primary study (Hazelton Laboratories, Inc., Acute Inhalation Toxicity-Rats, Project No. 183-195, May 18, 1973) rats were exposed to approximately 6 gm of test material for 1 hr and observed for a 14 day period. Several criteria (physical appearance and behavior, body and organ weight, gross and microscopic pathology) were used to evaluate toxicity. Treated rats displayed normal appearance and behavior throughout the course of the study. No treatment-related

toxicity or differences between treated and control groups were observed.

Additional data/information on the effects of different NPVs following pulmonary exposure was provided by the registrant to further support the waiver request. Although procedures and/or details were not provided for some of the referenced articles the results demonstrate a lack of toxicity/infectivity following pulmonary exposure with NPVs.

CLASSIFICATION: Acceptable. Toxicity Category IV. Although the referenced studies were not conducted under current guideline protocols the sum total of the information submitted is sufficient to satisfy the study requirement.

152A-14. Primary Eye Irritation Study. The applicant has requested a waiver for this study based on existing data. In a study performed by Hazelton Laboratories (1972), a single application (0.1 ml) of polyhedra or freed virions (concentrations not provided) from A. californica NPV was introduced into the conjunctival sac of the left eye of rabbits. No signs of eye or conjunctival irritation or corneal damage were noted throughout the course of the study (14 days).

<u>CLASSIFICATION</u>: Acceptable. Toxicity Category IV. The data are adequate to satisfy the primary eye irritation requirements for the EP. This study however, is not required for the technical grade active ingredient.

152A-15. Hypersensitivity Incidents. No cases or incidents of hypersensitivity to AcMNPV have been observed. The applicant must report any incidents of hypersensitivy to the Agency should any be observed in the future. As a note, the active ingredient (AcMNPV PIBs) is not a dermal sensitizer via topical application, but as observed with other NPVs may be a sensitizing agent via intracutaneous injection. Since the dermal route of exposure reflects the topical application route SAB would not recommend that the label contain a "sensitizer" warning.

152A-16. Cell Culture. The applicant has requested a waiver for this study based on existing data from the open literature. extensive literature review of cell culture studies using AcMNPV as the challenge inoculum demonstrated lack of viral replication and infectivity. Using different viral preparations (polyhedra [PIBs], hemolymph from AcMNPV-infected larvae, cell culture medium and cells, and alkali-liberated virions) 23 human cell lines were challenge with AcMNPV. In all instances, AcMNPV uptake occurred; however, once inside the cell viral replication did not occur. Moreover, such studies demonstrated rapid viral DNA degradation and lack of persistence in challenged mammalian cell lines. mammalian information also supports the general lack toxicity/infectivity of AcMNPV.

CLASSIFICATION: Acceptable.

Reviewed by:

J. Thomas McClintock, Ph.D., Microbiologist

Science Analysis Branch

Health Effects Division (H7509C)

Secondary Review:

Roy D. Sjoblad, Ph.D., Acting Section Head

Health Effects Division (H7509C)

DATE EVALUATION REPORT

STUDY TYPE: Product Identity

MRID NO.: 420730-00

CASWELL NO.: None Assigned

TEST MATERIAL: Autographa californica multiple-embedded nuclear

polydrosis virus (AcMNPV)

SYNONYMS: **GUSANO** 

STUDY NO.: FR91-12

CGI (formerly Espro, Inc.) SPONSOR:

> 7170 Standard Drive Hanover, MD 21076

TESTING FACILITIES: University of Florida

Institute of Food and Agricultural Sciences

Entomology and Nematology Department

Gainesville, FLA 32611-0740

TITLE OF REPORT: Product Chemistry

<u>AUTHOR</u>: D. M. Kolodny-Hirsch

REPORT ISSUED: May 31, 1991

CONCLUSION: The requirements for Series 151A-10, 151A-11, and 151A-16 have been partially satisfied. The data and information needed to fulfill the requirements for the remaining Series are incomplete.

CLASSIFICATION: Supplmentary. This study can be upgraded pending submission of data/information listed below.

Product Identity and Disclosure of Ingredients. (a). Product Identity. The active ingredient in GUSANO is the multipleembedded nuclear polyhedrosis virus of Autographa californica (AcMNPV) which was first isolated and described by Vail et al. (1971). The technical grade material is a lyophilized preparation containing 3% by weight of AcMNPV polyhedral inclusion bodies (PIBs). One reference from the open literature was submitted by the registrant supporting the identity of the active ingredient (a.i.).



(b). Confidential Statement of Formula (CSF). A CSF was provided by the registrant in support of this application. A revised CSF should be submitted stating that the product contains PIBs of the nuclear polyhedrosis virus of <u>Autographa californica</u> (alfalfa looper) as the a.i. The a.i. (i.e ACMNPV PIBs) and insect components/parts should be considered as the EP.

151A-11.	Manufacturing	Process.		

151A-12. Discussion of Formation of Unintentional Ingredients.

1511 18V BIDGADDION OF TOTAL OF ON THE ONE OF THE ONE OF THE OR THE ONE OF TH

151A-13. Analysis of Samples. The registrant states that "...the fundamental difference of this product from a traditional chemical renders this requirement inappropriate." This rationale is inappropriate, especially in light of the fact that the requirements for Series 151A-12 are inadequate and unacceptable. SAB agrees that analysis and identification of the insect inert components and/or impurities would be impossible; however, the registrant should provide a discussion on the methods and a statement of the precision and accuracy of the method used to analyze each sample or batch for the quantity of PIBs which, in turn, allows for the determination of the certified limits.

151A-15. Certification of Ingredient Limits. A CSF was provided by the registrant stating the certified limits of the a.i. and inerts in GUSANO.

The registrant states that the "procedure for sampling and enumerating polyhedral inclusion bodies of GUSANO are outlined in the article by Martignoni (1978)." This reference may in fact be adequate (reference not found); however this information must be presented and summarized especially if the procedure is modified.

To determine certified limits GUSANO was evaluated and the percent a.i. (PIBs/gm) determined to range from 3% to 10% with an activity titer of no less than "...41 thousand activity units/gram." The number of batches analyzed, the method used for enumeration and/or quantification of the number of PIBs per batch and the data for such calculations were not specified. The determination of the certified limits must be supported by an acceptable analytical method. This data/information should be submitted to the Agency.

The registrant also states that "No fecal coliform bacteria, or any other bacteria or other agents pathogenic for warm-blooded vertebrates are permitted as detected by culturing on differential bacteriological media, by intraperitoneal injection in mice and by oral administration to mice." Again, the registrant implies that specific methodologies are in place to assure QC/QA procedures. SAB recommends that each batch be analyzed by IP injection (10' PIBs/animal) study. The registrant should specify the methods to be used to assure that each batch is void of contaminating pathogens.

<u>151A-16.</u> Physical and Chemical Properties. The following physical and chemical properties were submitted for the end-use product:

<u>Property</u>	<u>Characteristics</u>		
Color	Tan to sandy brown		
Physical State	Solid		
Odor	Humus-like odor		
Density (loose)	0.186 g/cc or		
	11.6 lb/cu. ft.		
(tapped)	0.244 g/cc or		
	13.9 lb/cu. ft.		
Нд	6.1 using a 4.8% w/w		
_	suspension at 23.5°C		
Viscosity	Not required		
Miscibility	Not required		

Waivers were requested for Stability (151A-16[f]) and Storage Stability (151A-16[g]) studies. The following rationale was provided for each waiver request:

151A-16[f]. Several references were submitted by the registrant to support data waivers for stability. Specifically, various parameters were evaluated for their ability to inactivate both NPVs and GVs (granulosis viruses). One of the most important environmental factors considered was sunlight; whereby inactivation

occurs due to the ultraviolet portion of the spectrum. Information was submitted on pH demonstrating that infectious virions, released from the occlusion bodies, were inactivated at high alkaline (pH 12) and low acidic conditions (pH 1.2). The interaction between temperature and pH was also noted. When virions were suspended in an alkaline solution (pH 11) no inactivation was noted at  $21^{\circ}$ C; however at elevated temperatures ( $40^{\circ}$ C) the infectious virions were inactivated. Further, data from the open literature was presented demonstrating thermal inactivation of baculoviruses at various temperatures.

151A-16[q]. The technical grade of the product, GUSANO, is freezedried, packaged in a vacuum packed bag which is then inserted into a kraft-foil package. The proposed recommended storage is under refrigeration or freezing. In addition to references from the open literature, the registrant submitted raw data on the stability of analogous product/technical grade material (SPOD-X) subjected to different parameters and/or conditions. Two studies were presented: a long term and an accelerated shelf-life study. The long term study, which is currently in progress, will analyze lyophilized samples (loosely or vacuum packed) stored at 0°C and 25°C following 0, 3, 6, 12, and 24 months of storage. accelerated study, lyophilized samples (loosely or vacuum packed) subjected to different storage temperatures (25°C, 37°C, and 45°C) and bioassayed against second-instar S. exigua larvae, showed no loss in potency for 21 days at 37°C (LC<sub>50</sub> 1.3 x 10° PIBs/ml), but a ten-fold increase in the  $LC_{50}$  after 3 days at 45°C ( $LC_{50}$  1.0 x 10° PIBs/ml). The remaining data or a portion thereof, which was not submitted, will be shared between the two trials. The results from these two trials should be submitted to the Agency upon completion.

009848

Reviewed by:

J. Thomas McClintock, Ph.D., Microbiologist &

Science Analysis Branch

Health Effects Division (H7509C)

Secondary Review:

Roy D. Sjoblad, Ph.D., Acting Section Head RDA

Science Analysis Branch

Health Effects Division (H7509C)

DATE EVALUATION REPORT

Acute Intraperitoneal Toxicity Study

419357-02 MRID No.:

CASWELL NO.: None

Assigned

TEST MATERIAL: Autographa californica multiple-embedded nuclear

polydrosis virus (AcMNPV)

SYNONYMS: **GUSANO** 

STUDY NO.: S3197

<u>SPONSOR:</u> CGI (formerly Espro, Inc.)

7170 Standard Drive Hanover, MD 21076

TESTING FACILITIES: Cosmopolitan Safety Evaluations, Inc.

P. O. Box 71

Lafayette, NJ 07848

TITLE OF REPORT: Acute Intraperitoneal Toxicity/Pathogenicity

in Mice Dosed with Acal

AUTHOR: Geoffrey Robbins

June 18, 1991 REPORT ISSUED:

An intraperitoneal injection of approximately 1x10<sup>7</sup> PIBs/animal (0.385 mg/0.5 ml) of A. californica NPV did not produce any apparent signs of overt systemic toxicity following a 21-day test period.

CLASSIFICATION: Acceptable.

The test article consisted of STUDY DESIGN: A. Test Article. PIBs of A. californica NPV (Lot No. 050191). The test article was diluted into 0.5 ml sterile normal saline to a concentration of 1x10' PIBs/animal which was equivalent to 0.385 mg/0.5 ml/animal).

Young adult mice (AAI Mice, NIH) with weights Test Animal. ranging from 19.0 to 21.8 gm were used.

C. <u>Methods</u>. Twenty-nine male and 29 female mice were divided into 3 test groups which consisted of a control group (3 male and 3 female-no injection), a treated group (14 male and 14 female-0.385 mg of test substance/animal), and a vehicle control group (12 male and 12 female-0.5 ml sterile normal saline). Body weights were recorded prior to dosing and on Day 3, Day 7, Day 14, Day 21 and at death. Upon termination of the study all animals were sacrificed and the following organs examined: heart, lungs, spleen, liver, adrenals, kidneys, urinary bladder, stomach, small and large intestines, and reproductive organs. Body fluid and tissue were harvested for quantification of the microbial test article. Urine and feces were also collected for microbial quantification.

RESULTS: All treated and control group mice survived to the scheduled sacrifice date. There was no evidence of treatment-related signs following administration of the test material and throughout the course of the study. All treated animals exhibited normal body weight gain throughout the course of the study.

<u>DISCUSSION</u>: An intraperitoneal injection of approximately 1x10<sup>7</sup> PIBs/animal of <u>A</u>. <u>californica</u> NPV did not produce any apparent signs of overt systemic toxicity following a 21-day test period.

# U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

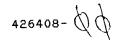
CROP GENETICS INTERNATIONAL 7170 STANDARD DRIVE HANOVER, MD 210761334

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 01/26/93. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

1 AK





# **Crop Genetics International**

7170 Standard Drive • Hanover, Maryland 21076-1334 USA (410) 712-7170 • TELEFAX (410) 712-0104

January 21, 1993

Mr. Phillip Hutton
Document Processing Desk (BIOTECH)
Office of Pesticide Programs-H7504C
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

Dear Mr. Hutton:

Your letter of 4 January 1993 described certain deficiencies in the Product Identity/Chemistry data requirements as submitted under FIFRA for new product registration of Gusano, <u>Autographa californica</u> nuclear polyhedrosis virus (EPA File Symbol 58971-G). In response to your review of the above application, we are submitting or resubmitting the following:

#### Vol. I - Administrative Materials

- Application for pesticide registration (EPA Form 8570-1).
- A revised CSF (EPA Form 8570-4) stating that the product contains polyhedral occlusion bodies of the nuclear polyhedrosis virus of <u>Autographa californica</u> (alfalfa looper) as the active ingredient.
- A revised product label.

# Vol. II - Product Identity/Chemistry

4264080 • A recently completed study (CGI Study No. 190IVR) which provides identifying restriction endonuclease patterns of the product strain of Gusano propagated from the specified production host <u>Trichoplusia</u> ni (cabbage looper).

Mr. Phillip Hutton January 22, 1993 Page -2-

# <u>Vol. III</u> - Product Identity/Chemistry

- 42640802 A revised Manufacturing Process (151A-11) which now includes a description of procedures to insure a healthy production insect colony.
  - A revised Discussion of Formation of Unintentional Ingredients (151A-12) which describes the specific tests to be used to detect fecal coliforms and mammalian pathogens or toxins. Note that the microbial assay methods cited from Martignoni (1978) are no longer used in this section.

<u>Vol. IV</u> - Product Identity/Chemistry

- 476408\$\psi 3 A revised Analysis of Samples (151A-13).
  - A revised Certification of Ingredient Limits (151A-15) incorporating data from recent Gusano production lots and including a detailed description of the quantification methods used for occlusion body concentration.

Also, please note that the completed storage stability studies requested in your letter of January 4, 1993 have previously been supplied in our resubmission of the Spod-X application (EPA File Symbol 58971-R), Vol. III, Guideline 151A-16g, MRID #42385502.

Furthermore, CGI will take appropriate steps to insure that this product is not used in close proximity to those areas identified by EPA as containing endangered species.

Sincerely,

James H. Davis

DATA EVALUATION REPORT

Reviewed by: Cindy Schaffer, Microbiologist, SAB/HED (5) Secondary Reviewer: J. Thomas McClintock, Ph.D., Microbiologist,

SAB/HED

STUDY TYPE:

CONCLUSION:

Product Analysis Information

MRID NO: 426408-01; 426408-02; 426408-03

Autographica Qálifornica TEST MATERIAL:

Nuclear Polyhedrosis

Virus

SYNONYMS: Gusano PROJECT NO: 190IVR

> Crop Genetics International, Hanover, MD SPONSOR:

Crop Genetics International, Hanover, MD TESTING FACILITY: TITLE OF REPORT: Restriction Endonuclease Analysis of Gusano, -embeddef

Autographica Californica Multiply Enveloped

Nuclear Polyhedrosis Virus; Supplement to

Product Chemistry.

AUTHOR(S): Nikolai van Beek, Douglas M. Kolodny-Hirsch

STUDY COMPLETED: 22 January 1993

Since the original submission included PST1 as the only restriction profile. SAB is assuming that the source of this profile is the same as used in production. Also, the following deficiencies are still outstanding on the resubmitted product analysis/chemistry package: 1. Data was not provided regarding

possible contaminants in the final product

that would result in the death of the bioassay insects. 2. The specific tests for detection, identification and enumeration evaluating seven types of bacteria listed in the previously submitted package were not

specified by the registrant. / 3 reference sited Martignoni (1978) was not

submitted.

CLASSIFICATION: UNACCEPTABLE

NOTE: This material contains CBI

PRODUCT\_ANALYSIS

151A-10 Product Analysis and Disclosure of Ingredients

Confidential Statement of Formula has been submitted. Gusano 3.3%, polyhedral occlusion bodies of the Muclear Polyhedrosis Xirus of <u>Autoqraphica</u> <u>californica</u> as an the active ingredient; and 96.7% Trichoplusia ni, as inerts.



# ADMINISTRATIVE MATERIAL

# Resubmission in Response to January 4, 1993 Letter

# Volume Number

I

# EPA's File Symbol

58971-G

Crop Genetics International 7170 Standard Drive Hanover, MD 21076

(410) 712-7170

Please read Instructions on r				prove	d. OMB No. 2	2070-0060	. Approval expires 11-30-93
	United States Environme Office of Pesticide P				Registr	ation	OPP Identifier Number
" SEPA	Washington,	DC 20460			Amend	ment	186782
	Application	for Pest	icide:	x	Other		
	S	ection I					
Company/Product Number		2.	EPA Product Ma	anagei	r .	3. Pi	roposed Classification
58971-G			Phil Hut	ton		_	lu
4. Company/Product (Name)		PN	Л#			X	None Restricted
Gusano			18				
<ol><li>Name and Address of Applic</li></ol>	cant (Include ZIP Code)						FIFRA Section 3(c)(3)
Crop Genetics In		I '	o)(I), my produc o:	I IS SI	milar or iden	ticai in co	omposition and labeling
7170 Standard Di							
Hanover, MD 210	076	E	PA Reg. No			·	
Check if this is a	new address	P	roduct Name			·	
	Sec	ction I I					
Amendment - Explain belo	w		Final printed	labels	in response	to	
Resubmission in response	to Agency letter dated 1/4/	93	Agency lette				
Notification - Explain below	· · · · · · · · · · · · · · · · · · ·	-	"Me Too" Ap				
			Other - expla	ain bei	ow.		
		ion III					
1. Material This Product Will		1,			Io T	O	
" "	nit Packaging	l	uble Packaging		2. Type of	7	
Yes*	Yes	Yes			x	Metal Plastic	
L≱ No [L	x No	X No			x	Glass Paper	
111-	"Yes," No. per nit Package wgt. container	If "Yes,"		per tainer		Other (S	pecify)
* Certification must be submitted.	nit Package wgt. container N/A I	Package v	_	tainer			
Location of Net Contents Info		f Retail Conta			Location of La		ions
x Label Conta	ainer			18	On Label		panying product
6. Manner In Which Label Is Aft		graph er glued	Oth	er (			)
·	Sten						
Contact Point (Complete iter		ction IV	al to be contacted	d. if ne	cessary, to p	rocess this	s application.)
Name Christine A. Di			ger, Pesti				e No. (Include Area Cooe)
	z & Connolly, Inc.		strations		-	202-	789 -3323
	Certification	on					6. Date Apolication
I certify that the statements I acknowledge that any know both under applicable law.	have made on this form and all wingly false or misleading state	attachments ment may be	thereto are true, punishable by fi	accura ne or i	ate and comp mprisonment	ete. or	RહcaivəJ (Stamped)
2. Signature		3. Title					
James HD	)		ce Preside d Developu	_	of Resea	rch	
4. Typed Name		5. Date					
/ James H. Davis		1	/22/93				69

EPA Form 8570-1 (Rev. 12-90)

Previous editions are obsolete.

White - EPA File Copy (origins)

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#### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling:
- 5. Three copies of any data submitted;
- Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission. Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant. Block A - Check the appropriate action for which you are submitting this form.

 $\underline{\sf SECTION\ I}$  - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.
- SECTION II This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.
- 1. Subject of cubmicsion Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
- 2. Type of Recall Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Specify the net contents of all retail containers for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
   5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc. 1-5. Self-explanatory.

6. EPA Use Only.

#### EEB REVIEW

<u>Pesticide Name</u>: Autographa californica Nuclear Polyhedrosis Virus

# 100.0.0 <u>Submission Purpose and Label Information</u>

# 100.1.0 <u>Submission Purpose and Pesticide Use</u>

Espro, Inc. has requested a Section 3 Registration for Gusano which contains Autographa californica a multicapsid nuclear polyhedrosis virus. The product is active against a number of caterpillars on the following crops: vegetable and cole crops; field crops; and trees of various species.

# 100.2.0 Formulation Information

# Wetable Powder Biological insecticide

ACTIVE INGREDIENT Polyhedral inclusion bodies (PIBs) of the alfalfa looper nuclear polyhedrosis virus.....3.5% Inert Ingredients.......96.5% 100.0%

This lot contains at least 10 billion PIB and 1 million beet activity units (AUs) per gram.

# 100.3.0 Application Methods, Directions, Rates

Gusano is a highly selective insecticide for use against caterpillars on the following crops using the listed rates:

	Million <u>Aus/acre</u>	grams <u>/acre</u>
Vegetables Tomatoes, lettuce cabbage, beans, peppers, celery, escarole, sweet-corn peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	10-50	10-50
Other Crops Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	10-50	10-50
Silvaculture Trees of various species	10-50	10-50

Gusano should be mixed with non-chlorinated water (near Ph 7.0) at the labeled rates and agitation should be used during mixing. The final formulation should be mixed for 10-30 minutes before use. Treatment should be made when

the insect larvae are young (early instars) and are actively feeding on foliage. If insect infestations are heavy, the higher label rates should be used. A spreader/sticker and ultraviolet screening agent may be needed to enhance the performance of this product.

### 100.4.0 Target Organisms

alfalfa looper, beet armyworm, black cutworm, bollworm, cabbage looper, celery looper, corn earworm, cotton leafperforator, diamondback moth, douglass fir tussock moth, eastern tent caterpillar, elm spanworm, european corn borer, fall armyworm, fall cankerworm. fall webworm, imported cabbageworm, orangestriped oakworm, pink bollworm, saltmarsh caterpillar, southwestern corn borer, soybean looper, tobacco budworm, tomato fruitworm, white cutworm

## 100.5.0 Precautionary Labeling

The label contains the following precautions:

KEEP OUT OF REACH OF CHILDREN

CAUTION: See additional precautionary statements and statements of practical treatment on the side panel

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS): (adequate)

ENVIRONMENTAL HAZARD STATEMENT: Do not contaminate water by cleaning equipment or disposing of wastes.

(Pesticide and container disposal directions are adequate)

# 101.0.0 Hazard Assessment

# 101.1.0 Discussion

The nuclear polyhedrosis virus used as the a.i. in this product is Autographa californica isolated from the alfalfa looper. The registrant has addressed each of the requirements for this type of product by supplying data from studies found in the open literature. This data will be used to justify waivers for each of these requirements.

A review of the studies submitted for this product demonstrated that no significant risk to nontarget wildlife should be expected from exposure of this product at the proposed use rates.

# 101.2.0 Likelihood at Adverse Effects to Nontarget Organisms

#### Avian Studies

No avian studies using this particular virus have been cited in the literature, however, studies using other NPVs have been reported. Spodoptera litura was fed to chicks (1.5x10<sup>10</sup> PIBs dosage) with no effect on behavior, temperature, weight gain, or feed conversion ratio. The gypsy moth NPV has been shown to have no effect on caged quail and several species of free-living birds tested in the wild. Twelve different NPVs have been tested on a number of bird species with no adverse effects being reported. Therefore no adverse effects to birds are expected from the use of Gusano.

# Fish Studies

Several tests have been conducted testing the effect of NPVs on fish including this one. Rainbow trout and sunfish were exposed to 10 and 10 polyhedra/gal of Autographa californica NPV and no mortality was observed. White suckers and trout were fed spruce budworm NPV at 10' polyhedra/qm body weight and no mortality or virus replication in the fish tissues was observed. Salmon and trout were exposed to Douglas-fir tussock moth NPV by injection, by adding the virus to their water, and by inoculating cell cultures (10° units/ml) with no evidence of toxicity or infection. The gypsy moth NPV did not adversely effect bluegill or brown trout, challenge by Neodiprion lecontei NPV (10 PIBs/g body weight per os) did not produce a response in rainbow trout, Mamestra brassicae NPV was shown to pass harmlessly through the alimentary tract of trout after feeding, and spruce budworm NPV was shown not to interfere with a cytopathogenic virus or infect a minnow cell line. Reports in the literature which tested Autographa californica in addition to other NPVs indicate that this NPV does not cause adverse effects to fish.

#### Mammalian Wildlife

These studies are required only when toxicology data are inadequate for assessment of hazard to wild mammals. The available toxicology data indicates that risk to wild mammals from the proposed uses of Gusano insecticide is minimal.

### Aquatic Invertebrate Studies

A literature search was conducted and no studies were found testing the effect of Autographa californica NPV on aquatic invertebrates. However, there were studies testing the effect of other NPVs on aquatic invertebrates. N. lecontei NPV did not produce any Daphnid mortality or prood size changes after 14 days with a dose of 2.4x10 PIBs/ml. The virus was not found in any of the fish tissue sectioned at the end of the study. Gypsy moth NPV had no effect on Daphnia, Chironomus, or Notonecta, and H. zea NPV had no effect on Daphnia. Based on these studies and the fact that aquatic invertebrates have frequent exposure to NPVs in nature with no documented adverse effects, Autographa californica NPV should not have any adverse on aquatic invertebrates.

# Estuarine and Marine Animal Studies

A search of the literature uncovered two studies using Autographa californica NPV and shrimp. White and brown shrimp injected with 10 virus rods or fed a diet containing up to 8000 polyhedra/ul of food produced no indication of virus toxicity or pathogenicity upon gross observations or examination of various shrimp tissue. The estuarine grass shrimp Palaemontes after being feed food pellets containing 10 polyhedra/pellet showed no differences in mortality or behavior between the treated and control shrimp after 30 days. The shrimp showed no evidence of virus infection, viral replication or cytopathogenic activity. From the results of these studies, Autographa californica should not cause adverse effects on estuarine and marine animals.

#### Nontarget Plant Studies

The NPVs are unique among the described viruses and are not biochemically or morphologically similar to plant viruses. To our knowledge, there are no reports in the literature of Baculoviruses (which includes this virus) as being toxic or pathogenic to plants or plants being affected in any way by these viruses. In view of this information, no nontarget plant hazard is expected from the proposed uses of Gusano insecticide.

# Honey Bee Studies

A review of the literature demonstrated that Autographa californica NPV had been tested on honey bee. A review of 6 publications contained in a literature review of the baculoviruses showed that NPVs from 6 lepidoptera larvae

(Autographa californica, Choristomeura fuiferana, Heliothis zea, Mamertra brassicae, Thymelicus lineola, and Neodiprion lecontei) were tested on honeybees and did not show any abnormalities or deleterious effects in egg production, brood rearing, worker and queen mortality, and general colony behavior. In addition, the NPVs S. frugipeda, Heliothis zea, Trichoplusia ni, Lymantria dispar, Hemerocampa (Orygia) pseudotsugata, and Neodiprion sertifer had been fed to honey bees (Aphis mellifera) in observation hives at a dose of 1x10 polyhedra/200 ml of 50% sucrose solution. differences were observed between treated and control colonies. From these results, it appears to the best of our knowledge that NPVs such as Autographa californica should not cause adverse effects to honey bees.

## Nontarget Beneficial Insect Studies

There are a number of literature citations concerning NPV testing on predators and parasites. The reports indicate that there does not seem to be an effect on predators (pentatomids, lacewings, ladybirds and scavenger beetles) that consume NPV infected larvae. Parasites also do not seem to be directly affected by NPVs. NPV infected Spodoptera litura larvae did not alter the development of the parasite Parasarchopaga misera and NPV infection in the lawn armyworm, Spodoptera maruitia, did not seem to affect parasitization by the solitary internal larval parasite, Apanteles marginiventris. However, the parasites host may die prematurely which would cause the This should only occur when the larvae not to develop. larvae are infected at an early stage (later infection would allow the parasites to develop) and generally the parasites tend to avoid parasitizing diseased larvae. From these results, it does not appear to the best of our knowledge that NPVs will cause adverse effects to predatory or beneficial insects.

# 101.3.0 Endangered Species Considerations

This product may be expected to be used throughout the United States with possible exposure to all endangered/ threatened species that are susceptible to this virus. Based on the toxicity and exposure data, EEB feels that there will not be a "may affect" situation for endangered mammals, birds, non-lepidopteran invertebrates, plants and aquatic species.

The use of Guano insecticide in Washington, Oregon, California and Florida, however, may affect endangered lepidopteran insect species. Based on information available to EEB, the following are counties in which the

use of this product may result in hazard to endangered/threatened species of lepidopterans:

## County, State

# Species of Concern

Los Angeles, CA

Contra Costa, CA Mendocino, CA San Francisco, CA San Mateo, CA

Monterey, CA
Kern, CA
Dade, FL
Monore, FL
Lane, OR
Pacific, WA
Tillamook, WA

El Segundo blue butterfly
Palos Verdes blue butterfly
Lange's metalmark butterfly
Lotis blue butterfly
Mission blue butterfly
Mission blue butterfly
San Bruno elfin butterfly
Smith's blue butterfly
Kern primrose sphinx moth
Schaus swallowtail butterfly
Oregon silverspot butterfly
Oregon silverspot butterfly

 In California the species and specific areas to be avoided are as follows:

Lotis blue butterfly - Mendocino County - 3 miles south of Mendocino City to Fort Bragg along a 2 mile corridor along Highway 1.

Lange's metalmark butterfly - Contra Costa County - Antioch Sand Dunes Wildlife Refuge.

Mission blue butterfly and San Bruno elfin butterfly - San Mateo County - San Bruno Mountain, Milgara Ridge, Skyline College (Guadalupe Canyon Parkway), Sweeney Ridge, and Montana Mountain.

Smith's blue butterfly - Monterey County - Seaside Marina coastal dune complex from the City of Monterey to Point Gorda, Fort Ord Military Reservation, Seaside Dunes, California Department of Fish and Game preserve near the mouth of the Salinas River, Monterey Sand Hills, Lobos State Preserve, Partington Canyon between Highway 1 and Partington Cove, Burns Creek, several west-facing canyons adjacent to Highway 1 between Malpaso and Garrapatacreeks, north-facing slopes adjacent to Carmel River between Boronda and Paso Hondo roads near Carmel Valley, Vasquez Knob, and Paraiso springs.

El Sequndo blue butterfly - Los Angeles County - International Airport and Chevron Refinery.

Kern primrose sphinx moth - Kern County - Walker Basin

- 2. In Florida, the insect virus, or any formulations thereof, should not be used in the Dade County Keys in Key Biscayne national Park, thence southward to Lower Metacumbe Key in Monroe County
- 3. The insect virus, or any formulations thereof, should not be near the Pacific Ocean in Tillamook County, Oregon and Pacific County, Washington, where the Oregon silverspot butterfly is known to occur.

The registrant will need to ensure that the use of this product does not cause a hazard to these endangered/ threatened species. Guano should not be applied near any of the habitats of these insects. If the product is to be used in any of the listed counties, the applicator should avoid the specific areas containing these insect habitats.

# 101.4.0 Adequacy of Toxicity Data

(See the Generic Data Table)

The registrant has addressed the data requirements outlined in the Pesticide Assessment Guidelines, Subdivision M.

Generic Data Requirements For Gusano

Data	Test	Use <sup>2</sup>	Does EPA	Bibliographic	Must Additional
Requirements	Substance	Patterns	Have Data?	Citation	Data Be Submitted?
§158.740 Microbial Pes	ticide Nontar	get Organis	m - Tier I		
Avian Testing					
154-16 Avian Acute Ora	ıl				
- bobwhite quail	TGAI	A,B,G	No		No <sup>4</sup>
- mallard duck	TGAI	A,B,G	No		No <sup>4</sup>
Aquatic Organism Testi	ng				
154-19 Freshwater Fish	LC50				
- rainbow trout	TGAI	A,B,G	No	~~-	No <sup>4</sup>
154-20 Freshwater Inve	ertebrate				
- <u>Daphnia magna</u>	TGAI	A,B,G	No		No <sup>4</sup>
154-21 Estuarine and M	Marine			*	
- animals	TGAI	A,B,G	No		No <sup>3</sup>

#### Additional Testing

154-22 Nontarget plant studies

- selected species	TGAI	A,B,G	No	***	No <sup>4</sup>
154-23 Nontarget insect t	esting		-		
- beneficials	TGAI	A,B,G	No		No <sup>4</sup>
154-24 Money bee testing					
- adult bees	TGAI	A,B,G	No		No <sup>4</sup>

<sup>1/</sup> TGAI = Technical Grade of the Active Ingredient; TEP = Typical End-Use Product.

# 101.5.0 Adequacy of Labeling

The precautionary labeling (see sec. 100.5.0) is adequate and no additions/modifications need to be made.

Endangered Species Labeling: Endangered species labeling is deferred until the Technical Bulletin information is made available by OPP.

# 102.0.0 Classification: N/A

## 103.0.0 Conclusions

EEB has reviewed the proposed Section 3 Registration of Gusano by Espro, Inc. for control of several insect species on vegetables, cole crops, field crops, and various tree species. The studies submitted by the registrant do not specifically address the testing requirements but can be used to grant waivers for each of the requirements. EEB concludes that risk to nontarget wildlife from the proposed uses of Gusano will be minimal to nonexistent.

# Endangered species considerations

The use of Gusano insecticide in Washington, Oregon, California and Florida may affect endangered Lepidopteran insect species. The specific locations of the endangered species in these areas are listed in section 101.3.0.

<sup>2/</sup> The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G= Forestry; H= Domestic, Outdoor; I = Indoor.

<sup>3/</sup> Only required if there will be exposure to the estuarine and marine environment (e.g. turf use)

<sup>4/</sup> The registrant submitted studies from the open literature that demonstrated a lack of adverse effects to the nontarget organisms in each testing category and the testing was waived.

<u> 128885</u>			
SHAUGHNESSEY	NO.		

REVIEW NO.

# EEB REVIEW

DATE: IN <u>12-5-9</u>	OUT NOV 17 1992	-	
FILE OR REG. NO			. 12
PETITION OR EXP. NO			
DATE OF SUBMISSION	7-9-91		
DATE RECEIVED BY EFED	12-5-91		
RD REQUESTED COMPLETION DAT	E12-19-92		
EEB ESTIMATED COMPLETION DA	TE		
RD ACTION CODE/TYPE OF REVI	EW010		
TYPE PRODUCT(S) : I, D, H, I			
PRODUCT MANAGER NO. Line	da Hollis/P. Hutton (PM	<u>[-18)</u>	
PRODUCT NAME(S)Autogra	pha Californica NPV		
COMPANY NAMEEs	pro, Inc.		
SUBMISSION PURPOSE <u>Secti</u>	on 3 Registration		
SHAUGH. NO. CHEMICA	.L	%	FORMULATION
128885 Autographa ca	alifornica NPV		3.5

#### EEB REVIEW

<u>Pesticide Name</u>: Autographa californica Nuclear Polyhedrosis Virus

# 100.0.0 <u>Submission Purpose and Label Information</u>

# 100.1.0 <u>Submission Purpose and Pesticide Use</u>

Espro, Inc. has requested a Section 3 Registration for Gusano which contains Autographa californica a multicapsid nuclear polyhedrosis virus. The product is active against a number of caterpillars on the following crops: vegetable and cole crops; field crops; and trees of various species.

#### 100.2.0 Formulation Information

# Wetable Powder Biological insecticide

ACTIVE INGREDIENT	
Polyhedral inclusion bodies (PIBs) of the	
alfalfa looper nuclear polyhedrosis virus3.5	ક
Inert Ingredients96.5	
TOTAL 100.0	

This lot contains at least 10 billion PIB and 1 million beet activity units (AUs) per gram.

# 100.3.0 Application Methods, Directions, Rates

Gusano is a highly selective insecticide for use against caterpillars on the following crops using the listed rates:

	Million <u>Aus/acre</u>	grams <u>/acre</u>
Vegetables Tomatoes, lettuce cabbage, beans, peppers, celery, escarole, sweet-corn peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	10-50 ,	10-50
Other Crops Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	10-50	10-50
Silvaculture Trees of various species	10-50	10-50

Gusano should be mixed with non-chlorinated water (near Ph 7.0) at the labeled rates and agitation should be used during mixing. The final formulation should be mixed for 10-30 minutes before use. Treatment should be made when

the insect larvae are young (early instars) and are actively feeding on foliage. If insect infestations are heavy, the higher label rates should be used. A spreader/sticker and ultraviolet screening agent may be needed to enhance the performance of this product.

# 100.4.0 Target Organisms

alfalfa looper, beet armyworm, black cutworm, bollworm, cabbage looper, celery looper, corn earworm, cotton leafperforator, diamondback moth, douglass fir tussock moth, eastern tent caterpillar, elm spanworm, european corn borer, fall armyworm, fall cankerworm. fall webworm, imported cabbageworm, orangestriped oakworm, pink bollworm, saltmarsh caterpillar, southwestern corn borer, soybean looper, tobacco budworm, tomato fruitworm, white cutworm

# 100.5.0 Precautionary Labeling

The label contains the following precautions:

KEEP OUT OF REACH OF CHILDREN

CAUTION: See additional precautionary statements and statements of practical treatment on the side panel

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS): (adequate)

ENVIRONMENTAL HAZARD STATEMENT: Do not contaminate water by cleaning equipment or disposing of wastes.

(Pesticide and container disposal directions are adequate)

# 101.0.0 Hazard Assessment

#### 101.1.0 Discussion

The nuclear polyhedrosis virus used as the a.i. in this product is Autographa californica isolated from the alfalfa looper. The registrant has addressed each of the requirements for this type of product by supplying data from studies found in the open literature. This data will be used to justify waivers for each of these requirements.

A review of the studies submitted for this product demonstrated that no significant risk to nontarget wildlife should be expected from exposure of this product at the proposed use rates.

# 101.2.0 Likelihood at Adverse Effects to Nontarget Organisms

## Avian Studies

No avian studies using this particular virus have been cited in the literature, however, studies using other NPVs have been reported. Spodoptera litura was fed to chicks (1.5x10 PIBs dosage) with no effect on behavior, temperature, weight gain, or feed conversion ratio. The gypsy moth NPV has been shown to have no effect on caged quail and several species of free-living birds tested in the wild. Twelve different NPVs have been tested on a number of bird species with no adverse effects being reported. Therefore no adverse effects to birds are expected from the use of Gusano.

### Fish Studies

Several tests have been conducted testing the effect of NPVs on fish including this one. Rainbow trout and sunfish were exposed to 10 and 10 polyhedra/gal of Autographa californica NPV and no mortality was observed. White suckers and trout were fed spruce budworm NPV at 10' polyhedra/qm body weight and no mortality or virus replication in the fish tissues was observed. Salmon and trout were exposed to Douglas-fir tussock moth NPV by injection, by adding the virus to their water, and by inoculating cell cultures (10 units/ml) with no evidence of toxicity or infection. The gypsy moth NPV did not adversely effect bluegill or brown trout, challenge by Neodiprion lecontei NPV (10<sup>6</sup> PIBs/g body weight per os) did not produce a response in rainbow trout, Mamestra brassicae NPV was shown to pass harmlessly through the alimentary tract of trout after feeding, and spruce budworm NPV was shown not to interfere with a cytopathogenic virus or infect a minnow cell line. Reports in the literature which tested Autographa californica in addition to other NPVs indicate that this NPV does not cause adverse effects to fish.

#### Mammalian Wildlife

These studies are required only when toxicology data are inadequate for assessment of hazard to wild mammals. The available toxicology data indicates that risk to wild mammals from the proposed uses of Gusano insecticide is minimal.

## Aquatic Invertebrate Studies

A literature search was conducted and no studies were found testing the effect of Autographa californica NPV on aquatic invertebrates. However, there were studies testing the effect of other NPVs on aquatic invertebrates. N. lecontei NPV did not produce any Daphnid mortality or prood size changes after 14 days with a dose of 2.4x10° PIBs/ml. The virus was not found in any of the fish tissue sectioned at the end of the study. Gypsy moth NPV had no effect on Daphnia, Chironomus, or Notonecta, and H. zea NPV had no effect on Based on these studies and the fact that aquatic invertebrates have frequent exposure to NPVs in nature with no documented adverse effects, Autographa californica NPV should not have any adverse on aquatic invertebrates.

### Estuarine and Marine Animal Studies

A search of the literature uncovered two studies using Autographa californica NPV and shrimp. White and brown shrimp injected with 10 virus rods or fed a diet containing up to 8000 polyhedra/ul of food produced no indication of virus toxicity or pathogenicity upon gross observations or examination of various shrimp tissue. The estuarine grass shrimp Palaemontes after being feed food pellets containing 10 polyhedra/pellet showed no differences in mortality or behavior between the treated and control shrimp after 30 days. The shrimp showed no evidence of virus infection, viral replication or cytopathogenic activity. From the results of these studies, Autographa californica should not cause adverse effects on estuarine and marine animals.

#### Nontarget Plant Studies

The NPVs are unique among the described viruses and are not biochemically or morphologically similar to plant viruses. To our knowledge, there are no reports in the literature of Baculoviruses (which includes this virus) as being toxic or pathogenic to plants or plants being affected in any way by these viruses. In view of this information, no nontarget plant hazard is expected from the proposed uses of Gusano insecticide.

#### Honey Bee Studies

A review of the literature demonstrated that Autographa californica NPV had been tested on honey bee. A review of 6 publications contained in a literature review of the baculoviruses showed that NPVs from 6 lepidoptera larvae

(Autographa californica, Choristomeura fuiferana, Heliothis zea, Mamertra brassicae, Thymelicus lineola, and Neodiprion lecontei) were tested on honeybees and did not show any abnormalities or deleterious effects in egg production, brood rearing, worker and queen mortality, and general colony behavior. In addition, the NPVs S. frugipeda, Heliothis zea, Trichoplusia ni, Lymantria dispar, Hemerocampa (Orygia) pseudotsugata, and Neodiprion sertifer had been fed to honey bees (Aphis mellifera) in observation hives at a dose of 1x10 polyhedra/200 ml of 50% sucrose solution. differences were observed between treated and control From these results, it appears to the best colonies. of our knowledge that NPVs such as Autographa californica should not cause adverse effects to honey bees.

# Nontarget Beneficial Insect Studies

There are a number of literature citations concerning NPV testing on predators and parasites. The reports indicate that there does not seem to be an effect on predators (pentatomids, lacewings, ladybirds and scavenger beetles) that consume NPV infected larvae. Parasites also do not seem to be directly affected by NPVs. NPV infected Spodoptera litura larvae did not alter the development of the parasite Parasarchopaga misera and NPV infection in the lawn armyworm, Spodoptera maruitia, did not seem to affect parasitization by the solitary internal larval parasite, Apanteles marginiventris. However, the parasites host may die prematurely which would cause the larvae not to develop. This should only occur when the larvae are infected at an early stage (later infection would allow the parasites to develop) and generally the parasites tend to avoid parasitizing diseased larvae. From these results, it does not appear to the best of our knowledge that NPVs will cause adverse effects to predatory or beneficial insects.

## 101.3.0 Endangered Species Considerations

This product may be expected to be used throughout the United States with possible exposure to all endangered/threatened species that are susceptible to this virus. Based on the toxicity and exposure data, EEB feels that there will not be a "may affect" situation for endangered mammals, birds, non-lepidopteran invertebrates, plants and aquatic species.

The use of Guano insecticide in Washington, Oregon, California and Florida, however, may affect endangered lepidopteran insect species. Based on information available to EEB, the following are counties in which the

use of this product may result in hazard to endangered/threatened species of lepidopterans:

# County, State

# Species of Concern

Los Angeles, CA

Contra Costa, CA Mendocino, CA San Francisco, CA San Mateo, CA

Monterey, CA
Kern, CA
Dade, FL
Monore, FL
Lane, OR
Pacific, WA
Tillamook, WA

El Segundo blue butterfly
Palos Verdes blue butterfly
Lange's metalmark butterfly
Lotis blue butterfly
Mission blue butterfly
Mission blue butterfly
San Bruno elfin butterfly
Smith's blue butterfly
Kern primrose sphinx moth
Schaus swallowtail butterfly
Oregon silverspot butterfly
Oregon silverspot butterfly
Oregon silverspot butterfly

1. In California the species and specific areas to be avoided are as follows:

Lotis blue butterfly - Mendocino County - 3 miles south of Mendocino City to Fort Bragg along a 2 mile corridor along Highway 1.

Lange's metalmark butterfly - Contra Costa County - Antioch Sand Dunes Wildlife Refuge.

Mission blue butterfly and San Bruno elfin butterfly - San Mateo County - San Bruno Mountain, Milgara Ridge, Skyline College (Guadalupe Canyon Parkway), Sweeney Ridge, and Montana Mountain.

Smith's blue butterfly - Monterey County - Seaside Marina coastal dune complex from the City of Monterey to Point Gorda, Fort Ord Military Reservation, Seaside Dunes, California Department of Fish and Game preserve near the mouth of the Salinas River, Monterey Sand Hills, Lobos State Preserve, Partington Canyon between Highway 1 and Partington Cove, Burns Creek, several west-facing canyons adjacent to Highway 1 between Malpaso and Garrapatacreeks, north-facing slopes adjacent to Carmel River between Boronda and Paso Hondo roads near Carmel Valley, Vasquez Knob, and Paraiso springs.

El Sequndo blue butterfly - Los Angeles County - International Airport and Chevron Refinery.

Kern primrose sphinx moth - Kern County - Walker Basin

- 2. In Florida, the insect virus, or any formulations thereof, should not be used in the Dade County Keys in Key Biscayne national Park, thence southward to Lower Metacumbe Key in Monroe County
- 3. The insect virus, or any formulations thereof, should not be near the Pacific Ocean in Tillamook County, Oregon and Pacific County, Washington, where the Oregon silverspot butterfly is known to occur.

The registrant will need to ensure that the use of this product does not cause a hazard to these endangered/ threatened species. Guano should not be applied near any of the habitats of these insects. If the product is to be used in any of the listed counties, the applicator should avoid the specific areas containing these insect habitats.

# 101.4.0 Adequacy of Toxicity Data

(See the Generic Data Table)

The registrant has addressed the data requirements outlined in the Pesticide Assessment Guidelines, Subdivision M.

Generic Data Requirements For Gusano

Data	Test	Use <sup>2</sup>	Does EPA	Bibliographic	Must Additional
Requirements	Substance	Patterns	Have Data?	Citation	Data Be Submitted?
§158.740 Microbial Pes	ticide Nontar	get Organis	<u>n</u> - Tier I		
Avian Testing					
154-16 Avian Acute Ora	ıL				
- bobwhite quail	TGAI	A,B,G	No		No <sup>4</sup>
- mallard duck	TGAI	A,B,G	No		No <sup>4</sup>
Aquatic Organism Testi	ng				
154-19 Freshwater Fish	LC <sub>50</sub>				
- rainbow trout	TGAI	A,B,G	No		No <sup>4</sup>
154-20 Freshwater Inve	ertebrate				
- <u>Daphnia magna</u>	TGAI	A,B,G	No		No <sup>4</sup>
154-21 Estuarine and M	Marine				
- animals	TGAI	A,B,G	No		No <sup>3</sup>

#### Additional Testing

154-22 Nontarget plant studies

	- selected species	TGAI	A,B,G	No	 No <sup>4</sup>
154-2	Nontarget insect tes	sting			
	- beneficials	TGAI	A,B,G	No	 No <sup>4</sup>
154-24	4 Honey bee testing				
	- adult bees	TGAI	A,B,G	No	 No <sup>4</sup>

<sup>1/</sup> TGAI = Technical Grade of the Active Ingredient; TEP = Typical End-Use Product.

# 101.5.0 Adequacy of Labeling

The precautionary labeling (see sec. 100.5.0) is adequate and no additions/modifications need to be made.

Endangered Species Labeling: Endangered species labeling is deferred until the Technical Bulletin information is made available by OPP.

# 102.0.0 Classification: N/A

## 103.0.0 Conclusions

EEB has reviewed the proposed Section 3 Registration of Gusano by Espro, Inc. for control of several insect species on vegetables, cole crops, field crops, and various tree species. The studies submitted by the registrant do not specifically address the testing requirements but can be used to grant waivers for each of the requirements. EEB concludes that risk to nontarget wildlife from the proposed uses of Gusano will be minimal to nonexistent.

# Endangered species considerations

The use of Gusano insecticide in Washington, Oregon, California and Florida may affect endangered Lepidopteran insect species. The specific locations of the endangered species in these areas are listed in section 101.3.0.

<sup>2/</sup> The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G= Forestry; H= Domestic, Outdoor; I = Indoor.

<sup>3/</sup> Only required if there will be exposure to the estuarine and marine environment (e.g. turf use)

<sup>4/</sup> The registrant submitted studies from the open literature that demonstrated a lack of adverse effects to the nontarget organisms in each testing category and the testing was waived.

This product should not used in close proximity to these areas to ensure that no exposure to the endangered species occurs.

David Bays, Microbiologist Ecological Effects Branch

Ecological Fate and Effects Division (H7507C)

Leslie W. Touart, Head Section 1

Ecological Effects Branch

Ecological Fate and Effects Division (H7507C)

Anthony F. Maciorowski, Chief

Ecological Effects Branch

Ecological Fate and Effects Division (H7507C)

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12/ B- 1/17/2

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(A) SEPA United States Environment Office of Pesticide Programment Washington, Application			Registr	ation	OPP Identifier Number
Washington	DC 20460	)	Amend	ment	169343
Application	for Pes	sticide: [	_ Other		109343
So	ection I				<u>, , , , , , , , , , , , , , , , , , , </u>
Company/Product Number		2. EPA Product Man	ager	3. Pr	roposed Classification
58788-G		Phil Hutto	on		l
Company/Product (Name)		PM#		X	None Restricted
GUSANO		18			
5. Name and Address of Applicant ( <i>Include ZIP Code</i> ) <b>Crop Genetics International</b>					FIFRA Section 3(c)(3)
10150 Old Columbia Road		(b)(i), my product i	s similar or ider	itical in co	omposition and labeling
Columbia, Maryland 21046					
		EPA Reg. No			
Check if this is a new address		Product Name			
Sec	tion I I				
Amandment Evalain holaw		Final printed la	abels in response	to	
Amendment - Explain below		Agency letter			
X Resubmission in response to Agency letter dated 7/28	8/93	"Me Too" Appl	ication.		
Notification - Explain below.		Other - explain	n below.		
Explanation: Use additional page(s) if necessary. (For section	an Lond Co				
Explanation. Ose additional page(s) in necessary. (For section	on rand Se	cuon n.)			
Sect	ion III				
Material This Product Will Be Packaged In:					
Child-Resistant Packaging Unit Packaging	Water 9	Soluble Packaging	2. Type of	_	
Yes* Yes		es		Metal Plastic	
No No		lo		Glass	
If "Yes," No. per	If "Yes,		er	Paper Other (S	necify)
* Certification must be Unit Package wgt. container	Packag	e wgt. conta	iner -	] 011.01 (0)	,
submitted.  3. Location of Net Contents Information  4. Size(s) of	f Betail Co	ntainer	5. Location of La	abel Direct	ions
	i i iciali co	TILLING!	On Labe	I	
Label Container  6. Manner In Which Label Is Affixed To Product Litho	graph			ing accom	panying product
Pape	r glued	Other	· (		)
Send Send	ction IV				
Contact Point (Complete items directly below for identification)		dual to be contacted,	if necessary, to p	rocess this	s application.)
Name	Title			Telephon	e No. (Include Area Code)
0	<u> </u>				6 Data Application
Certification		eta thoroto aro truo. 20	courate and comp	lete	Date Application     Received
I certify that the statements I have made on this form and all I acknowledge that any knowingly false or misleading stater	ment may	be punishable by fine	or imprisonment	or	(Stamped)
both under applicable law.	•	-			
2. Signature	3. Title				
James HD-	Vic	e President o		.	
		and Developm	nent		
4. Typed Name James H. Davis	5. Date	August 26, 1	.993		

EPA Form 8570-1 (Rev. 12-90)

# **Paperwork Reduction Act Notice and Instructions**

# Paperwork Reduction Act Notice

Public reporting burden for this collection of information is estimated to average of 0.85 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

### **Instructions**

#### General

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

- Offer to Pay Statement (EPA Form 8570-22, -23, or -24). (If not exempted by 40 CFR 162.9-1(b).)
- 2. Confidential Statement of Formula (EPA Form 8570-4).
- 3. Five copies of draft labeling.
- 4. Three copies of any data submitted.

**Submission of Labeling -** Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on  $8\ 1/2\ x\ 11$  inch paper or as a mockup of the proposed label. If prepared as a mockup it should be constructed in such a way as to facilitate storage in an  $8\ 1/2\ x\ 11$  inch file. Mockup labels significantly smaller than  $8\ 1/2\ x\ 11$  inches should be mounted on  $8\ 1/2\ x\ 11$  inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

#### Specific

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A , for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Section I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both Registration and Amended Registration actions.

- Company/Product Number Insert your company number, if
  one has been assigned. This number may have been assigned
  to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
- Date Fill in the appropriate date.
- 3. **Product Manager** If known, fill in the name and number of the **Product Manager**.
- Proposed Classification Specify the proposed classification for this product.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

- An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

#### Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

 Subject of Amendment - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

#### Packaging and Container Information

Section III - This Section must be completed for all applications submitted in connection with New Registration.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
- Type of Retail Container Indicate type of container in which product will be marketed.
- Location of Net Contents Specify the net contents of all retail containers for your product.
- Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- Location of Use Directions Indicate the location of the use directions for your product.
- Manner in which label is affixed to product Indicate the method product labeling is attached to retail container.

#### **Contact Point**

Section IV - This Section must be completed for all Registration and Amended Registration applications.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

EPA Form 8570-1 (Rev. 12-90)

PM-18

# **ENVIRONMENTAL PROTECTION AGENCY**

[PF-564; FRL-4066-2]

# **Pesticide Tolerance Petitions**

AGENCY: Environmental Protection Agency (EPA).

**ACTION:** Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions (PP) and food and feed additive petitions (FAP) proposing the establishment of regulations for residues of certain pesticide chemicals in or on certain agricultural mmodities. It also announces two amended petitions and a corrected petition.

DRESSES: By mail, submit written comments to: Public Response and Program Sources Branch, Field Operations Division (H7506C), Office of Pesticide Tograms, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1128, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1128 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Registration Division H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 A St., SW., Washington, DC 20460. In person, contact the PM named in each tition at the following office location/telephone number:

Product Manager	Office location/telephone number	Address
George LaRocca (PM-13)	Rm. 202, CM #2, 703-557-2400	1921 Jefferson Davis Hwy., Arlington, VA.
	Rm. 213, CM #2, 703-305-7690	Do.
Dennis Edwards (PM-19)	Rm. 207, CM #2, 703-305-5386	Do.
Susan Lewis (PM-21)	Rm. 227, CM #2, 703-305-6900	Do.
Cynthia Giles-Parker (PM-22)	Rm. 229, CM #2, 703-305-5540	Do.
oanne Miller (PM-23)	Rm. 237, CM #2, 703-305-7830	Do.
Robert Taylor (PM-25)	Rm. 241, CM #2, 703-305-6800	Do.
lovt Jamerson (PM-43)	Rm. 716C, CM #2, 703-305-5310	Do.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions and food/feed additive petitions as follows proposing the establishment and/or amendment of regulations for regulations for residues of certain pesticide chemicals in or on various agricultural commodities.

# **Initial Filings**

1. PP 2F4072. Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419-8300, proposes to amend 40 CFR 180.408 by establishing a regulation to permit combined residues of the fungicide metalaxyl (N-(2,6-dimethylphenyl)-N-(methoxyacetyl)aniline methyl ester) and its metabolites containing the 2,6-

- dimethylaniline moiety, and N-(2-hydroxymethyl-6-methylphenyl)-N-methoxyacetyl) aniline methyl ester, each expressed as metalaxyl equivalents in or on brassica (cole) leafy vegetable crop grouping at 5.0 parts per million (ppm). (PM-21)
- 2. PP 2F4075. BASF Corp., Agricultural Chemicals, P.O. Box 13528, Research Triangle Park, NC 27709-3528, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on rice grain at 0.1 ppm and rice straw at 0.5 ppm. (PM-25)
- 3. PP 2F4076. EcoScience Corp., 85 North Whitney St., P.O. Box 300, Amherst, MA 01004, proposes to amend 40 CFR part 180 by establishing a egulation for permanent exemption from the requirement of a tolerance for Metarhizium anisopliae in or on all raw agricultural commodities. (PM-18)
- 4. PP 2F4077. FMC Corp., Agricultural Chemicals Group, 1735 Market St., Philadelphia, PA 19103, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of 2-(2-chlorophenyl) ethyl-4,4-dimethyl-3-isoxazolidinone in or on cottonseed at 0.05 ppm. (PM-25)
- 5. PP 2F4079. FMC Corp., Agricultural Chemicals Group, 1735 Market St., Philadelphia, PA 19103, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of (±)cis,trans-3-(2,2-dichloro-ethenyl)-2,2-dimethylcyclopropane carboxylate cypermethrin and its metabolites dichlorovinyl acid (DCVA) and m-phenoxybenzoic acid (MPB Acid) in or on sorghum grain at 3.0 ppm, sorghum fodder/forage at 12.0 ppm, sorghum, green and chopped/silage at 6.0 ppm, and sorghum hay at 31.0 ppm. (PM-13)
- 6. PP 2F4081. Monsanto Co., Suite 1100, 700 14th St., NW., Washington, C 20005, proposes to amend 40 CFR 180.364 by establishing a regulation to permit residues of glyphosate (N-(phosphonomethyl) glycine) and its metabolite aminomethylphosphonic acid resulting from the application of the isopropylamine salt of glyphosate and/or the monoammonium salt of glyphosate in or on almond hulls at 25 ppm and tree nut crops at 1.0 ppm. (PM-25)
- 7. PP 2F4082. McLaughlin Gormley King Co., 8810 Tenth Ave. North, Minneapolis, MN 55427-4372, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of insecticide (S)-cyano(3-phenoxyphenyl)methyl-(S)-4-chloro-alpha-(1-methylethyl)benzeneacetate in or on cocoa at 1.0 ppm. (PM-13)
- 8. PP 2F4086. Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419-8300, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of the fungicide propiconazole (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole)), and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in or on oat grain at 0.1 ppm, and oat straw at 1.0 ppm. (PM-21)

- 9. PP 2F4089. Espro, Inc., 1015 15th St., NW., Suite 500, Washington, DC 20005, proposes to amend 40 CFR part 180, by establishing a regulation exempting acal from the requirement of a tolerance. (PM-18)
- 10. PP 2F4090. Espro, Inc., 1015 15th St., NW., Suite 500, Washington, DC 20005, proposes to amend 40 CFR part 180 by establishing a regulation to exempt cydx from requirement of a tolerance. (PM-18)
- 11. PP 2F4091. E. I. du Pont de Nemours Co., Inc., Walker's Mill, Barley Mill Plaza, P.O. Box 80038, Wilmington, DE 19880-0038, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of the insecticide methomyl (S-methyl N-[methylcarbamoyl] thioacetimidate in or on sugarbeet tops at 1.0 ppm. (PM-19)
- 12. PP 2F4097. Jellinek, Schwartz, Connolly, Freshman, Inc., 1015 15th St., NW., Washington, DC 20005, proposes to amend 40 CFR part 180 by establishing a regulation to permit the residues of pentachloronitrobenzene (PCNB) in or on potatoes at 2.0 ppm. (PM-21)
- 13. PP 2F4098. Versar, Inc., RiskFocus Division, 6850 Versar Center, Springfield, VA 22151, proposes to amend 40 CFR part 180, by establishing a regulation to permit residues of microbial pesticide Dr. Biosedge (Puccinia canaliculata) in or on food crops. (PM-21)
- 14. PP 2F4100. ICI Americas, Inc., Agricultural Products, Concord Pike & New Murphy Rd., Wilmington, DE 19897, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of lambdacyhalothrin [1-alpha(S),3-alpha(Z)]-(±)-cyano-(3-phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate] in or on both dry bulb onions and garlic at 0.1 ppm. (PM-13)
- 15. PP 2F4103. FMC Corp., Agricultural Chemicals Group, 1735 Market 3t., Philadelphia, PA 19103, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of (±)-a-cyano-(3-phenoxyphenyl)l (±)cis,trans-3-(2,2-dichloro-ethenyl)-2,2-dimethylcyclopropane carboxylate (cypermethrin) and its metabolites dichlorovinyl acid (DCVA) and m-phenoxybenzoic acid (MPB Acid) in or on tomato fruit at 0.5 ppm. (PM-13)
- 16. PP 2F4104. DowElanco, 9002 Purdue Rd., Indianapolis, IN 46268-1189, proposes to amend 40 CFR 180.417 by increasing the existing tolerance in milk from 0.01 ppm to 0.05 ppm, and establishing a tolerance for residues of triclopyr (3,5,6-trichloro-2-pyridinyloxyacetic acid) in or on apples at 0.05 ppm. (PM-25)
- 17. PP 2F4105. Ciba-Geigy Corp., Agricultural Division, P.O. Box 18300, Greensboro, NC 27419-8300, proposes to amend 40 CFR 180.408 by establishing a regulation to permit residues of the fungicide metalaxyl [N-(2,6-dimethylphenyl)-N-(methoxyacetyl)analine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)anilina methyl ester, each expressed as metalaxyl equivalents in or on nongrass animal feed forage at 6.0 ppm, nongrass animal feed hay at 20.0 ppm. (PM-21)

- 18. PP 2F4106. DowElanco, 9002 Purdue Rd., Indianapolis, IN 46268-1189, proposes to amend 40 CFR part 180 by establishing a regulation to permit combined residues of the soil microbiocide nitrapyrin [2-chloro-6-(trichloromethyl)pyridine and its metabolite, 6-trichloropicolinic acid in or on wheat forage at 2 ppm, wheat grain at 0.5 ppm, and wheat straw at 6 ppm. (PM-23)
- 19. PP 2F4107. Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419-8300, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of difenoconazole 1-(2-[4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan-2-yl-methyl)-1H-1,2,4-triazole in or on wheat forage at 0.1 ppm, wheat straw at 0.1 ppm, barley forage at 0.1 ppm, and barley straw at 0.1 ppm. (PM-21)
- 20. PP 2F4109. ICI Agricultural Products, Wilmington, DE 19897, proposes to amend 40 CFR 180.378 by establishing a regulation to permit residues of '1alpha(S),3alpha(Z]-(±cyano-(3-phenoxyphenyl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate in or on corn fodder at 3.0 ppm, corn grain field, pop and seed at 0.05 ppm, corn grain dust at 0.1 ppm, and corn silage at 1.0 ppm. (PM-13)
- 21. PP 2F4110. Nor-Am Chemical Co., 3509 Silverside Rd., P.O. Box 7495, Wilmington, DE 19803, proposes to amend 40 CFR 180.287 by establishing a regulation to permit the residues of the insecticide amitraz (N'-[2,4-dimethylphenyl]-N-[[(2,4-dimethylphenyl)imino] methyl]]-N-methylmethanimidamide) and its metabolites N-(2,4-dimethylphenyl)-N-methylmethanimide (both calculated as the parent) in or on liver at 0.4 ppm, fat at 0.2 ppm, and meat-by-products at 0.6 ppm of cattle, goats, hogs, horses, and sheep. (PM-19)
- 22. PP 2F4114. ICI Americas, Inc., Agricultural Products, Wilmington, DE 9897, proposes to amend 40 CFR 180.438 by establishing a regulation to permit residues of lambda-cyhalothrin [1 alpha(S), 3 alpha(Z)]-(+)-cyano(3-phenoxyphenyl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate in or on peanut hulls at 0.05 ppm and peanut nutmeats at 0.05 ppm. (PM-13)
- 23. FAP 2H5618. Nor-Am Chemical Co., P.O. Box 7495, 3509 Silverside Rd., Wilmington, DE 19803, proposes to amend 40 CFR part 185 by establishing a food additive regulation to permit residues of insecticide miticide amitraz (N'-[2,4-dimethylphenyl]-N-[[2,4-dimethylphenyl]-N-methyl-methanimidamide) and its metabolites N-(2,4-dimethylphenyl)-N-methyl formamide and N-(2,4-dimethylphenyl)-N-methylmethanimidamide (both calculated as parent compound) in or on imported dried hops at 75 ppm. (PM-19)
- 24. FAP 2H5619. Sandoz Crop Protection Corp., 1300 East Touhy Ave., Des Plains. IL 60018, proposes to amend 40 CFR part 186 by establishing a feed additive for fluvalinate import tolerance in or on apple pomace, dry, at 2.0 ppm and hops, dried, at 15.0 ppm. (PM-13)

- 25. FAP 2H5621. BASF Corp., Agricultural Products Group, P.O. Box 13528, Research Triangle Park, NC 27709-3528, proposes to amend 40 CFR part 186 by establishing a feed additive regulation to permit residues of (ethoxyimino)butyl-5-(2-ethylthio)prop in or on canola rape soapstock at 160.0 ppm and canola meal at 40.0 ppm. (PM-25)
- 26. FAP 2H5625. E.I. du Pont de Nemours & Co., Wilmington, DE 19880-0038, proposes to amend 40 CFR part 186 by establishing a feed additive petition for residues of the fungicide benomyl, methyl 1-butylcarbamoyl-2-benzimidazolecarbamate, in or on raisin waste at 50.0 ppm. (PM-21)
- 27. FAP 2H5626. EcoScience Corp., 85 North Whitney St., P.O. Box 300, Amherst, MA 01004, proposes to amend 40 CFR parts 185 and 186 by exempting from the requirement of a tolerance in or on processed food and animal feed Metarhizium anisopliae used for roach control. (PM-18)
- 28. FAP 2H5627. FMC Corp., Agricultural Chemical Group, 1735 Market St., Philadelphia, PA 10103, proposes to amend 40 CFR part 185 by establishing a food additive petition for cypermethrin (±)-a-cyano-(3-phenoxyphenyl)methyl (±)cis,trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate (cypermethrin) and its metabolites dichlorovinyl acid (DCVA) and m-phenoxybenzoic acid (MPB Acid) in or on sorghum flour at 1.5 ppm. (PM-13)
- 29. FAP 2H5628. Miles Inc., 8400 Hawthorn Rd., P.O. Box 4913, Kansas City, MO 64120-0013, proposes to amend 40 CFR part 185 by establishing a food additive petition for tebuconazole (a-[2-(4-chlorophenyl) ethyl]-a-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol) in or on peanut oil at 0.5 ppm and peanut soapstock at 0.5 ppm. (PM-21)
- 30. FAP 2H5629. Monsanto Co., Suite 1100, 700 14th St., NW., Washington, DC 20005, proposes to amend 40 CFR part 185 by establishing a feed additive petition to permit residues of the herbicide alachlor (2-chloro-2',6'-diethyl-N-(methoxymethyl) acetamide) and its metabolites (calculated as alachlor) in or on soybean grain dust at 2.0 ppm and soybean grain hulls at 1.0 ppm. (PM-25)
- 31. FAP 2H5630. BASF Corp., Agricultural Chemicals, P.O. Box 13528, Research Triangle Park, NC 27709-3528, proposes to amend 40 CFR part 186 by establishing a feed additive petition to permit combined residues of Poast herbicide, 2-[1-ethoxyimino)butyl]-5-[2-(ethylthio) propyl]-3-hydroxy-2-cyclohexen-1-one and its metabolites containing the 2-cyclohexen-1-one, in or on rice hulls at 0.2 ppm and rice bran at 0.2 ppm. (PM-25)
- 32. FAP 2H5631. FMC Corp., Agricultural Chemicals Group, 1735 Market St., Philadelphia, PA 19103, proposes to amend 40 CFR part 185 by establishing a food additive petition to permit the residues of cypermethrin (±)-a-cyano-(3-phenoxyphenyl)methyl(±)cis,trans-3-(2,2-dichloro-ethenyl)-2,2-dimethylcyclopropane carboxlylate (cypermethrin) and its metabolites dichlorovinyl acid (DCVA) and m-phenoxybenzoic acid (MPB Acid) in or on tomato juice at 0.1 ppm, tomato puree at 0.1 ppm, tomato catsup at 0.2 ppm, tomato wet pomace at 1.0 ppm, and tomato dry pomace at 11.0 ppm. (PM-25)

- 33. FAP 2H5633. IR-4, Cook College, P.O. Box 231, Rutgers, State University of New Jersey, New Brunswick, NJ 08903-0231, proposes to amend 40 CFR part 185 by establishing a regulation to permit the residues of insecticide cyfluthrin (cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate) in or on dried hops at 4.0 ppm. (PM-43)
- 34. FAP 2H5634. DowElanco, 9002 Purdue Rd., Indianapolis, IN 46268-1189, proposes to amend 40 CFR part 185 by establishing a food additive petition to permit combined residues of the soil microbiocide nitrapyrin [2-chloro-6-(trichloromethyl)pyridine] and its metabolite, 6-chloropicolinic acid, in or on wheat bran at 2 ppm and wheat shorts at 1 ppm. (PM-23)
- 35. FAP 2H5635. Monsanto Co., Suite 1100, 700 14th St., NW., Washington, DC 20005, proposes to amend 40 CFR 185.3500 by establishing a food additive petition to permit combined residues of glyphosate (N-phosphonomethyl)glycine) and its metabolites aminomethylphosphonic acid resulting from the application of the isopropylamine salt of glyphosate and/or the monoammonium salt of the glyphosate in or on wheat milling fractions (excluding flour) at 12 ppm. (PM-25)
- 36. FAP 2H5636. Miles, Inc., 8400 Hawthorn Rd., P.O. Box 4913, Kansas City, MO 64120-0013, proposes to amend 40 CFR part 186 by establishing a feed additive regulation to permit the residues of Bayleton, 1-(4-chlorophenoxy)-3.3-dimethyl-1-(1H-2,4-triazol-1-yl)-2-butanone, in or on pineapple bran at 5.0 ppm. (PM-22)
- 37. FAP 2H5638. American Cyanamid Co., P.O. Box 0400, Princeton, NJ 08543-0400, proposes to amend 40 CFR part 186 by establishing a feed additive regulation to permit residues of the herbicide difenzoquat, (1,2-dimethyl-3,5-diphenyl-1H-pyrazolium ion), derived from application of the methyl sulfate salt and the cation, in or on barley milled fractions (except flour), and wheat milled fractions (except flour) at 1.0 ppm. (PM-23)
- 38. FAP 2H5639. Valent U.S.A. Corp., 1333 N. California Blvd., Suite 600, P.O. Box 8025, Walnut Creek, CA 94594-8025, proposes to amend 40 CFR part 185 by establishing a food additive regulation to permit residues of fenpropathrin, alpha-cyano-3-phenoxybenzyl 2,2,3,3-tetramethylcyclopropanecarboxylate, in or on cotton seed oil at 3 ppm, raisins at 15 ppm, orange oil at 160 ppm, cottonseed soapstock at 2 ppm, raisin waste at 45 ppm, and grape pomace, wet and dry at 35 ppm, orange pulp, dry at 8 ppm. (PM-13)
- 39. FAP 2H5640. Ciba-Geigy Corp., Agricultural Division, P.O. Box 18300, Greensboro, NC 27419-8300, proposes to amend 40 CFR parts 185 and 186 by establishing a food/feed additive petition to permit combined residues of cyromazine (N-cyclopropyl-1,3,5-triazine-2,4,6-triamine) and its principal metabolite melamine (1,3,5-triazine-2,4,6-triamine) calculated as cyromazine in or on processed tomato products at 1.2 ppm and dry tomato pomace at 1.6 ppm. (PM-18)

# **Amended Petitions**

40. FAP 2H5623. BASF Corp., Agricultural Chemicals, P.O. Box 13528, Research Triangle Park, NC 27709-3528, proposes to amend 40 CFR part 185 by establishing a regulation to permit combined residues of vinclozolin, 3-(3,5dichloro-phenyl)-5-ethenyl-5-methyl-2,4 oxazolidinedione, and its metabolites containing the 3,5-dichloroaniline moiety in or on potato dry peel at 3.0 ppm. Notice of this petition originally published in the Federal Register of March 11, 1992 (57 FR 8658), and proposed establishing tolerances for potato dry peel at 3.0 ppm and potato granules, flakes, and chips at 0.2 ppm. (PM-21)

41. FAP 2H5624. Nor-Am Chemical Co., 3509 Silverside Rd., P.O. Box 7495, Wilmington, DE 19803, proposes to amend 40 CFR part 185 by establishing a food additive tolerance for phenmedipham [3methoxycarbonylaminophenyl-3'-methylcarbanilate] in or on sugar beet pulp, dehydrated at 0.5 ppm, and sugar beet molasses at 0.2 ppm. Notice of this petition originally published in the Federal Register of March 11, 1992 (57 FR 8659), and proposed amending 40 CFR 186.278 to establish a feed additive tolerance for phenmedipham in or on sugar beet pulp, dehydrated at 0.5 ppm, and sugar beet molasses at 0.2 ppm. (PM-25)

# **Corrected Petition**

42. PP 2F4039. In the Federal Register of March 11, 1992 (57 FR 8658), EPA issued incorrectly an initial filing of PP 2F4039. It is corrected to read as follows: PP 2F4039. Scentry, Inc., 610 Central Ave., Billings, MT 59102, proposes to amend 40 CFR part 180 by establishing a regulation to exempt from the requirement of a tolerance the insect pheromone containing the active ingredients [E/Z]-4-tridecen-1-yl acetates in or on all raw agricultural commodities. (PM-18)

Authority: 7 U.S.C. 136a.

Dated: May 19, 1992

Anne E. Lindsay, Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 92-???? Filed ??-??-92; 8:45 a.m.]

BILLING CODE 6560-50-F

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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

James H. Davis
CROP GENETICS INTERNATIONAL CORP.
10150 Old Columbia Road
Columbia, Md. 21046-1704

Dear Mr. Davis:

Subject: Internal Transfer of Pesticide Registrations From Company Number 58971 to Company Number 58788

Pursuant to your request in your letter and transfer agreement of June 9, 1993, we have approved the transfer of the following registrations from CROP GENETICS INTERNATIONAL CORP., company number 58971, to CROP GENETICS INTERNATIONAL CORP., company number 58788.

The effective date of these changes is June 25, 1993.

Registered Products	Common	old EPA	New EPA
	Chemical Name	Reg. No.	Reg. No.
Spod Wettable Powder	Polyhedral	58971-1	58788-1

The following products are pending registrations and therefore cannot be marketed until they are registered.

Pending Products	Old Pending No.	New Pending No.
GYPCHEK	58971-E (2)	58788-E (2)
GUSANO	58971-G (3)	58788-G (3)
Cyd-X	58971-U (4)	58788 <b>-</b> U (4)

The effective date of issuance of the new EPA registration number is June 25, 1993. You should indicate the new company designation and new EPA Reg. No. on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number or other suitable descrip-

tion the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Reg. No. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Reg. No. listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as they had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquire products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his notion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active sec. 3 and sec. 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

Sincerely,

James A.

James A. Tompkins Acting Section Head for Administrative Processing Section

Registration Support Branch

Registration Division (H7505W)

#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

James H. Davis
Vice President of
Research and Development
Crop Genetics International
10150 Old Columbia Road
Columbia, MD 21046-1704

JUL 28 1993

131 | +34992

Subject: GUSANO, EPA File Symbol 58971-G
Your resubmission dated 1/22/93

Dear Dr. Davis:

The resubmission referred to above, submitted in connection with registration under FIFRA as amended, is not acceptable at this time for the reasons stated below. Please refer to the Agency letter of 1/4/93.

- 1. Provide a more detailed discussion regarding the expected restriction endonuclease (REN) patterns of AcMNPV propagated in the production host as well as indicating whether or not the AcMNPV isolate used in the REN Analysis is the same isolate intended for registration. During our review of this resubmission, one restriction pattern was observed and the data resubmitted by you in response to this deficiency did not adequately address this issue.
- 2. Provide data regarding possible contaminants in the final product which would result in the death of the bioassay insects as well as providing information regrding the specific test(s) used for detection, identification and enumeration of possible microbial contaminants for the seven types of bacteria listed in your original submission.

Sincerely,

Phil Hutton, PM 18

Insecticide/Rodenticide Branch Registration Division H7505C

cc: Christine Dively

	Jellinek, Schwartz, Connolly							
& Freshman, Inc. CONCURRENCES								
SYMBOL	H7575C							
SURNAME	Hollis						·	
DATE	7/16/93							
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EPA Form 1320-1A (1/90)

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This product should not used in close proximity to these areas to ensure that no exposure to the endangered species occurs.

David Bays, Microbiologist Ecological Effects Branch

Ecological Fate and Effects Division (H7507C)

Leslie W. Touart, Head Section 1

Ecological Effects Branch

Ecological Fate and Effects Division (H7507C)

Anthony F. Maciorowski, Chief

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Ecological Effects Branch

Ecological Fate and Effects Division (H7507C)

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person, bring comments to: Environmental Protection Agency, rm. 1128. CM =2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted in any comment concerning this notice may be claimed confidential by marking anv part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. All written comments will be available for public inspection in rm. 1128 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Registration Division (H7505C), Attn: (Product Manager (PM) named in each registration), Office of Pesticide Programs, 401 M St., SW., Washington, DC 20460.

In person: Contact the PM named in each registration at the following office location/telephone number:

Product Manager	Office location/ telephone number	Address
PM10 Richard Mountfort	Rm. 208, CM #2 (703–305– 6502).	Environmental Protection Agency 1921 Jefferson Davis Hwy Arlington, VA 22202
PM 18 Phili Hutton	Rm. 213, CM #2 (703-305- 7690).	-Do-

[OPP-30331: FRL 4055-1]

**ACTION:** Notice.

# Certain Companies; Applications to Register Pesticide Products

**AGENCY:** Environmental Protection Agency (EPA).

SUMMARY: This notice announces receipt of applications to register pesticide products containing active ingredients not included in any previously registered products pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATES: Written comments must be submitted by June 1, 1992.

ADDRESSES: By mail submit comments identified by the document control number [OPP-30331] and the registration/file number, attention Product Manager (PM) named in each application at the following address: Public Response and Program Resources Branch, Field Operations Division [H7506C], Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In

supplementary information: EPA received applications as follows to register pesticide products containing active ingredients not included in any previously registered products pursuant to the provisions of section 3(c)(4) of FIFRA. Notice of receipt of these applications does not imply a decision by the Agency on the applications.

#### Products Containing Active Ingredients Not Included In Any Previously Registered Products

1. File Symbol: 1021-RAEN. Applicant: McLaughlin Gormley King Company, 8810 Tenth Avenue North, Minneapolis, MN 55427. Product name: Nylar Concentrate 2607. Insecticide. Active ingredient: 2-[1-Methyl-2-(4-phenoxyphenoxy) ethoxy] pyridine 1.30 percent. Proposed classification/Use:

None. For indoor use on fleas in nonfood areas. (PM 10)

2. File Symbol: 1021-RANG.
Applicant: McLaughlin Gormley King
Co. Product name: Nylar 10EC.
Insecticide. Active ingredient: 2-[1Methyl-2-(4-phenoxyphenoxy) ethoxy]
pyridine 10 percent. Proposed
classification/Use: None. For control of
cockroaches and fleas in the home and
nonfood areas of various buildings. (PM
10)

3. File Symbol: 1021-RARO.
Applicant: McLaughlin Gormley King
Co. Product name: Nylar 50%
Concentrate. Insecticide. Active
ingredient: 2-{1-Methyl-2-(4phenoxyphenoxy} ethoxy] pyridine 50
percent. Proposed classification/Use:
None. For manufacturing use only. (PM

4. File Symbol: 1021-RAEE. Applicant: McLaughlin Gormley King Co. Product name: Nylar Pressurized Spray 2618. Insecticide. Active ingredients: 2-[1-Methyl-2-(4-phenoxyphenoxy) ethoxy] pyridine 0.015 percent, tetramethrin [(1cyclohexane-1,2-dicarboximido) methyl 2,2-dimethyl-3-(2-methylpropenyl) cyclopropanecarboxylate] 0.400 percent, and cis + trans 3-phenoxybenzyl-(1RS, 3RS; 1RS, 3SR)-2;2-dimethyl-3-(2methylprop-l-enyl) cyclopropanecarboxylate 0.300 percent. Proposed classification/Use: None. For indoor use on fleas, brown dog ticks, and carpet beetles in nonfood areas. (PM 10)

5. File Symbol: 1021-RAEG. Applicant: McLaughlin Gormley King Co. Product name: Nylar Total Release Fogger 2620. Insecticide. Active ingredients: 2-[1-Methyl-2-(4-phenoxyphenoxy) ethoxy] pyridine 0.100 percent, pyrethrins 0.050 percent, N-octyl bicycloheptene dicarboximide 0.400 percent, permethrin [(3-phenoxyphenyl) methyl (+ or -) cistrans-3-(2,2-dichloroethenyl) 2.2dimethylcyclopropanecarboxylate | 0.400 percent, and related compounds 0.035 percent. Proposed classification/Use: None. For control of various insects in the home and nonfood areas of various buildings. (PM 10)

6. File Symbol: 10308-RR. Applicant: Sumitomo Chemical Co., Ltd. c/o Technology Services Group, 1101 17th St., NW., Suite 500, Washington, DC 20036. Product name: Sumilarv Technical Grade. Insecticide. Active ingredient: 2-[1-Methyl-2-(4-phenoxyphenoxy] ethoxy] pyridine 97 percent. Proposed classification/Use: None. For formulating use only. (PM 10)

7. File Symbol: 64296–G. Applicant: EcoScience Corporation, 85 North Whitney St., Amherst, MA 01002. Product name: Bio-Path Roach Control Chamber. Biological Insecticide. Active ingredient: Metarhizium anisopliae 0.35 percent. Proposed classification/Use: None. For the control of roaches in residential, commercial, industrial, and institutional areas. (PM 18)

8. File Symbol: 64296-E. Applicant: EcoScience Corp. Product name: Bio-Path Insects Technical. Biological Insecticide. Active ingredient: Metarhizium anisopliae 100 percent. Proposed classification/Use: None. For use in manufacture of indoor and outdoor pest control products. (PM 18)

9. File Symbol: 64296—R. Applicant: EcoScience Corporation, 1 Innovation Drive, Worcester, MA 01605. Product name: Bio-Path Fly Control Chamber. Biological Insecticide. Active ingredients: *Metarhizium anisopliae* and 9-tricosene 3.80 and .10 percent respectively. Proposed classification/ Use: None. For the control of flies in residential, commercial, agricultural, and food and nonfood indoor areas. (PM 18)

10. File Symbol: 432-TAU. Applicant: Roussel Bio Corporation, 170 Beaver Brook Road, Lincoln Park, NJ 07035. Product name: Bio-Path Technical. Biological Insecticide. Active ingredient: Metarhizium anisopliae 100 percent. Proposed classification/Use: None. For use in manufacture of indoor and outdoor residential pest control products. (PM 18)

11. File Symbol: 432-TAR. Applicant: Roussel Bio Corporation, 170 Beaver Brook Road, Lincoln Park, NJ 07035. Product name: Bio-Path Biological Roach Control System. Biological Insecticide. Active ingredient: *Metarhizium anisopliae* 0.35 percent. Proposed classification/Use: None. For the control of roaches in residential, commercial, industrial, and institutional indoor food and nonfood areas. (PM 18)

12. File Symbol: 58971—U. Applicant: Crop Genetics International, 7170
Standard Drive, Hanover, MD 21076.
Product name: Cyd-X. Biological Insecticide. Active ingredient: Granular inclusion bodies (GIBS) of the codling moth granulosis virus 0.2 percent.
Proposed classification/Use: None. For use against the codling moth on pears, apples, and walnuts. (PM 18)

13. File Symbol: 58971–G. Applicant:
Crop Genetics International. Product
name: Gusano. Biological Insecticide.
Active ingredient: Polyhedral inclusion
bodies (PIBS) of the alfalfa looper
nuclear polyhedrosis virus 3.5 percent.
Proposed classification/Use: None. For
the control of caterpillars on vegetables,
cotton, alfalfa, wheat, and other food
crops and silvaculture (trees of various
species). (PM 18)

14. File Symbol: 58971–R. Applicant: Crop Genetics International, 7170 Standard Drive, Hanover, MD 21076.
Product name: Spod-X. Biological
Insecticide. Active ingredient:
Polyhedral inclusion bodies (PIBS) of the
beet armyworm nuclear polyhedrosis
virus 2.9 percent. Proposed
classification/Use: None. For use
against the beet armyworm on food
crops and floriculture. (PM 18)

Notice of approval or denial of an application to register a pesticide product will be announced in the Federal Register. The procedure for requesting data will be given in the Federal Register if an application is approved.

Comments received within the specified time period will be considered before a final decision is made; comments received after the time specified will be considered only to the extent possible without delaying processing of the application.

Written comments filed pursuant to this notice, will be available in the Public Response and Program Resources Branch, Fields Operation Division office at the address provided from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. It is suggested that persons interested in reviewing the application file, telephone the FOD office (703–305–5805), to ensure that the file is available on the date of intended visit.

Authority: 7 U.S.C. 136. Dated: April 21, 1992.

#### Frank Sanders,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 92-10238 Filed 4-30-82; 8:45 am] BILLING CODE 5660-50-F

[OPP-34027; FRL 4057-2]

Pesticide Reregistration Eligibility
Document for Sodium and Calcium
Hypochlorite; Availability for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: This notice announces the availability of the final Reregistration Eligibility Document (RED) for sodium and calcium hypochlorite and opens a public comment period. The RED is the Agency's formal regulatory assessment of the health and environmental data base for sodium and calcium hypochlorite and presents the Agency's determination regarding which uses of sodium and calcium hypochlorite are eligible for reregistration.

Le Date 12/20/9/

# NEW CHEMICAL/FIRST FOOD USE SCREEN

1.	. FILE SYMBOL/REG NO. (RSERB) 58971-G	
2.	. TOLERANCE PETITION NO. (RSERE)	
3.	. CHEMICAL NAME (RSERB) AUTOGRAPHA CALI	FORNICA MULTI-CAPSID NUCLEAR POLYHEDROSIS
4.	. PESTICIDE CHEMICAL CODE (RSERB) 1	28885-1
5.	PRODUCT NAME (RSERB) GUSANO	<u> </u>
6.	. PM (RSERB) 18 7. PM	TRAN REVIEWER (PM) Linda a. Hollis (18)
	DATE OF RECEIPT (RSERB) 6/14/91	
9.	. USE PATTERS (PM) On IN for the a	central of caterpillars of various insu
		(EPA Receipt Date Plus 3 Days)
		(EPA Receipt Date Plus 3 Days)
11.	1. DATE OF TRANSHISSION TO EED (PH)/	(M Receipt Date Plus 5 Days)
	A 10 C	(RSERB) (HED Receipt Date Plus 7 Days)
13.	4. HED REVIEWER (HED) MCC1, NTOC.	<u>K</u> ,
14.	A. HED REVIEW COMPLETION DATE (HED)	2/21/91
15.	5. RECORD NUMBER (PM)	
REG:	EGISTRANT PROSE CONTACT IMPORNATION (PM)	
Det	ate of Contact	STATUS OF PACKAGE
Per	erson Contacted	Passed Screen
	Title	
Dec	ecision & Comments	(Documentation attached)
		•

# CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC) REQUEST FORM\*

cr#:<u>41-0094</u>

REQUESTOR NAME:_	LUCY J. TRAII		REQUEST DATE 2 03 9
TEL.: (305-6979	ORG.: RSB	ROO	M: 716 MAIL CODE:
GGT ATTH GTTP	(DIA"\B	R./SEC.)	
CSF ATTACHED:	Canadan di Ladinani - ladin Ye		
		tem A and the chemical nate Items A through C.	iame in item B.
U NO II CSF I	is not attached comple	te Items A through C.	
A. INFORMATION REC	DUIRED:		
Check Applicable Category	<b>L</b> :		
☐ Provide PCC and	l Tolerance Exemption	Status For Food-Use Inc	ert Ingredient(s)
☐ Provide PCC for	Non-Food Use Inert I	ngredient (s)	_
☑ Provide PCC for	Active Ingredient(s)		
Provide PCC for	Dye		
		or Use in Formulation	
Other (Describe):	:		
B. INGREDIENT INFO	RMATIÓN:		
Ingredient No. 1:		Ingredient No. 2:	
•	HA CALIFORNICA M	•	
Chem. NameCAPSID NU	JCLEAR POLYHEDROS		
Trade Name:		Trade Name:	
G. G. D. N.		CAS Reg. No.:	
Ingredient No. 3:		Ingredient No. 4:	
2-18-0-1-1-1-1-1-1		augi outour 1100 ti	•
Chem. Name:		Chem. Name:	
True I NT.		Trade Name:	
CAS Des No.		<del></del>	
		_	
C. PESTICIDE PRODUC	T INFORMATION:		
C. I Editolph I Robot			
EPA Reg. No./File Symbo		oductName: GUSANO	
Registrant: ESPRO,			ood-Use Pesticide: TYES N
Percent in Formulation (	(For Fragrance/Dyes o	nly):	
IFORMATION REPORTE	D:		
Ingredient No. 1: ,		Ingredient No. 2:	
***************************************	:885-1	PCC:	<u> </u>
OL. STATUS:		TOL STATUS:	
ther inf.: <u>Now</u>	<u>Chemiral</u>	OTHER INF.:	
Ingredient No. 3:		Ingredient No. 4:	•
CC.		PCC:	
OL STATUS:		TOL STATUS:	
THER INF.:		OTHER INF.:	
rolated Br LINDA	EAN	1.47.5	191
opleted By: LING4	7.4117	Data Completed: 12/03	<u>[11]</u> F.S.

This product should not used in close proximity to these areas to ensure that no exposure to the endangered species occurs.

David Bays, Microbiologist

Ecological Effects Branch

Ecological Fate and Effects Division (H7507C)

Leslie W. Touart, Head Section 1

Ecological Effects Branch

Ecological Fate and Effects Division (H7507C)

Anthony F. Maciorowski, Chief

Ecological Effects Branch

Ecological Fate and Effects Division (H7507C)

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11/17/2

L(hTo

160 429325 25 13 JAN 14 1998

Christine A. Dively
Jellinek, Schwartz, Connolly & Freshman, Inc.
1015 15th Street N.W.
Suite 500
Washington, DC 20005

Subject: Gusano - <u>Autographa</u> californica nuclear polyhedrosis

virus

EPA File Symbol 58971-G

Response to Review

Dear Mrs. Dively:

The submission referred to above, submitted in connection with registration under FIFRA, as amended is unacceptable at this time. The following deficiencies and/or data gaps must be met before this product can be reviewed any further.

# I. Product Identity/Chemistry Data Requirements

provide a detailed discussion regarding the expected restriction endonuclease (REN) patterns of AcMNPV propagated in various host, elaborating on any differences which might occur. Provide information indicating whether or not the AcMNPV isolate used in the REN analysis is the same isolate to be used for registration. In the event that the isolates are different, provide a REN analysis of the active ingredient. You should be advised that a significant difference between the AcMNPV isolates may result in a reevaluation of the mammalian toxicology waiver requests.

clarify the derivation of the viral preparation used in the REN analysis. Submit a revised CSF stating that the product contains PIBs of the nuclear polyhedrosis virus of <u>Autographa californica</u> (alfalfa looper) as the active ingredient. This statement along with "insect parts" should also be placed on the label under the heading "Ingredients Statement".

provide data regarding the type of other contaminants which would result in the death of the bioassay insects.

CONCURRENCES								
SYMBOL	H7505C							
SURNAME	Hollis		-					
DATE	1-4-93						•	
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provide information regarding the specific test(s) used for identification and enumeration of microbial contaminants for the seven types of bacteria that you have listed.

provide the methods/protocols and specify the specific screens for the detection of significant mammalian pathogens. Perform an intraperitoneal injection (10° PIBs/animal) or an acute oral screen (endpoints should included signs of clinical toxicity, mortality) for each independent batch.

a statement of the precision and accuracy of this method. The number of batches analyzed the method as provide a discussion of the Analytical Method used as well as number of batches analyzed, the method used for enumeration and/or quantification of the number of PIBs per batch and the data for such calculations have not been specified. would allow for the determination of the certified limits.

provide the Agency with the reference cited Martignoni (1978) and submit a summary of the "procedure for sampling and enumerating polyhedral inclusions bodies of GUSANO.

- specify that QC/QA procedures are in place to ensure a healthy or disease-free insect colony.
- upon completion, submit the results from the storage stability studies.
- Endangered Species Considerations

The use of GUSANO insecticide in Washington, California and Florida may affect endangered Lepidopteran The specific locations of the endangered insect species. species in these areas can be found in the attachment. This product should not be used in close proximity to these areas to ensure that no exposure to the endangered species occurs.

This application will be kept open for a period of 75 days to give you an opportunity to correct the deficiencies listed above. If you find that you need more time to satisfy the requirements, you should request an extension and commit yourself to satisfy the deficiencies within a reasonable state period of time. If you do not comply with this procedure, the Agency may administratively withdraw your application from further consideration, and retire this file without further notice to you in accordance with the policy established by PR Notice 75-4 of August 27, 1975. Once this

CONCURRENCES						
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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

3

is done, you will have to submit a complete new application should you wish to pursue the registration of your product after the application has been withdrawn.

If you have any questions regarding this matter, please feel free to contact Linda A. Hollis of my staff @ (703) 305-6397.

Sincerely yours,

Philip O. Hutton, PM 18

Insecticide/Rodenticide Branch Registration Division H7505C

**ATTACHMENTS** 

	CONCURRENCES							
SYMBOL	1 11 ( )							
SURNAME )	Hollis							
DATE )	1-4-93			**************	******************************			
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EPA Form 1320-1A (1/90)

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# **ENVIRONMENTAL PROTECTION AGENCY**

40 CFR Part 180

[PP 2F4089/R2036; FRL-4753-2]

RIN 2070-AB78

Polyhedral Occlusion Bodies of Autographa Californica Nuclear Polyhedrosis Virus; Exemption from the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This rule establishes an exemption from the requirement of a pesticide tolerance for residues of the microbial pest control agent *Autographa californica* nuclear polyhedrosis virus in or on all raw agricultural commodities. The product Gusano is an insecticidal virus product containing the polyhedral occlusion bodies of the naturally occurring *Autographa californica* nuclear polyhedrosis virus (Family: Baculoviridae). This tolerance exemption was requested by Crop Genetics International. This regulation eliminates the need to establish a maximum permissible level for residues of *Autographa californica* nuclear polyhedrosis virus.

**EFFECTIVE DATE:** This regulation becomes effective (insert date of publication in the Federal Register).

ADDRESSES: Written objections, identified by the document control number, [PP 2F4089/R2036], may be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing request to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

FOR FURTHER INFORMATION CONTACT: By mail: Phillip O. Hutton, Product Manager (PM) 18, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 207, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-7690.

**SUPPLEMENTARY INFORMATION:** In the Federal Register of June 10, 1992 (57 FR 24645), EPA issued a notice that it had received PP 2F4089 from Espro, Inc., requesting that 40 CFR part 180 be amended to establish a tolerance for acal (the company and product, renamed "Gusano," have since been acquired

by Crop Genetics International, 10150 Old Columbia Rd., Columbia, MD 21046). Gusano contains the polyhedral occlusion bodies of *A. californica* nuclear polyhedrosis virus and is proposed for use in or on all raw agricultural commodities when used to control the alfalfa looper.

No comments were received in response to the notice of filing.

# Residue Chemistry Data

Although Gusano bioinsecticide will be applied on a variety of vegetable and silvaculture crops at rates varying from 5 to 50 grams per acre, residue chemistry data were not required. Such data were determined to be necessary only if the submitted toxicology studies indicate that additional Tier II or III toxicology data would be required as specified in 40 CFR 158.165(e). The submitted toxicology data for this use indicate that the product is of low mammalian toxicity; therefore, Tier II or III data were not required.

# **Toxicology Data**

Toxicology data requirements in support of this exemption from the requirement of a tolerance were satisfied via data waivers from the open scientific literature. These waivers include literature from an acute oral toxicity/ pathogenicity study in the rat, an acute pulmonary toxicity/pathogenicity study in the rat, an acute dermal toxicity study in the rabbit, and a primary eye irritation study in the rabbit. Findings from the open scientific literature showed no toxic, pathogenic, or adverse effects.

Reference Dose (RfD) and maximum permissible intake (MPI) considerations are not relevant to this petition because of the low toxicity and lack of pathogenicity or infectivity as reported in the open scientific literature.

Based on the information cited above, the Agency has determined that the potential acute toxicity/pathogenicity of *Autographa californica* nuclear polyhedrosis virus is sufficiently low to support the proposed exemption from the requirement of a tolerance on all raw agricultural commodities. Thus, a tolerance for the active ingredient *Autographa californica* nuclear polyhedrosis virus is not necessary to protect the public health. Therefore, 40 CFR part 180 is amended as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections and/or request a hearing with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a

reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a "significant regulatory action" as an action that is likely to result in a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations or recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of the Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

# List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated:

MAR - 9 100-

Douglas D. Campt,

Director, Office of Pesticide Programs.

conv of the original.

Therefore, 40 CFR part 180 is amended as follows:

# PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 346a and 371.

2. In subpart D, by adding new § 180.1125, to read as follows:

§ 180.1125 Polyhedral occlusion bodies of Autographa californica nuclear polyhedrosis virus; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the microbial pest control agent *Autographa californica* nuclear polyhedrosis virus in or on all raw agricultural commodities.

[FR Doc. 94-????? Filed ??-??-94; 8:45 am]

BILLING CODE 6560-50-F

JELLINEK, SCHWARTZ & CONNOLLY, INC.

Hand Delivered

April 12, 1994

Mr. Philip O. Hutton U.S. EPA: Worker Protection Standard c/o NCI Information Systems 8260 Greensboro Drive, Suite 400 McLean, VA 22102

70051-43

Re:

Submission of Worker Protection Standard Label Amendments for GUSANO

(EPA Reg. No. 58788-3)

Dear Mr. Hutton:

Enclosed please find EPA Form 8570-1, Application for Pesticide Amendment, five copies of the current labeling for GUSANO (EPA Reg. No. 58788-3) which includes the proposed Worker Protection Standard language. Because this product was registered on March 25, 1994 (and thus the current labeling is the same as the proposed for this exercise), I am enclosing only the five copies of the label.

#### **Certification Statement**

I certify that the revised labeling being submitted for this product is in complete accordance with the labeling requirements of PR Notice 93-7, which reflects the requirements of EPA's labeling regulations for worker protection statements (40 CFR part 156, subpart K). Where exact language is specified in the PR Notice I have used that language exactly, in the location specified. I further certify that no revisions are being submitted other than those directed by PR Notice 93-7. I understand that it would be a violation of FIFRA if I or my supplemental registrants were to sell or distribute this product after April 21, 1994, without amended labeling complying with the requirements of 40 CFR part 156, subject K.

# **Toxicity Profile**

GUSANO is classified as follows for acute toxicity.

Oral Toxicity	Category Waived
Dermal Toxicity	Category Waived
Inhalation Toxicity	Category Waived
Dermal Irritation	Category Waived
Eye Irritation	Category Waived

All acute toxicity data requirements were waived by EPA based on absence of biological activity in mammals.

Please do not hesitate to contact me at (202) 789-3323 or Curt Lunchick at (202) 789-3297 if you have any questions concerning this submission or if you require additional information.

Sincerely,

Christine A. Dively

Jellinek, Schwartz & Connolly, Inc. Authorized Representative for Crop Genetics International

Christine A. Dively-

Enclosures

cc: James Davis, Crop Genetics International

riease read instructions on reverse detore completing form	·-	Form App	roved. OMB No.	2070-0060	. Approval expires 11-30-93	
United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460 Application for Pesticide:  Registration Amendment Other Other						
Sec	ction i				. 144	
Company/Product Number	2	2. EPA Product Man	ager	3. Pr	roposed Classification	
58788-3		Phillip O.	Hutton		1	
Company/Product (Name)     GUSANO	F	°м# 18		X	None Restricted	
5. Name and Address of Applicant (Include ZIP Code)	6	6. Expedited Rev	/lew. In accord	ance with	FIFRA Section 3(c)(3)	
Crop Genetics International 10150 Old Columbia Road Columbia, MD 21046	(b)(i), my product is similar or identical in composition and labeling to:					
Check if this is a new address		Product Name				
Cook		100001110				
Secti	ion I I			<del></del> -		
Amendment - Explain below		Final printed la Agency letter	abels in response dated	to		
Resubmission in response to Agency letter dated		"Me Too" App	lication.			
Notification - Explain below.		Other - explair	n below.			
Amendment to meet Worker Protection St	Explanation: Use additional page(s) if necessary. (For section I and Section II.)  Amendment to meet Worker Protection Standard (WPS) requirements; additional certification statements are attached.					
Section	n III					
Material This Product Will Be Packaged In:			<u>, , , , , , , , , , , , , , , , , , , </u>			
Child-Resistant Packaging Unit Packaging	Water Sc	oluble Packaging	2. Type o	f Container		
☐ Yes* ☐ Yes	Ye	·c	<u> </u>	Metal		
	lН'°			Plastic		
No ·   No	No	•		Glass		
If "Yes," No. per	If "Yes,"	No. p	er —	Paper Other (S	pecify)	
Certification must be Unit Package wgt. container	Package	wgt. conta	iner		F	
submitted.				ahal Disasi	tion o	
3. Location of Net Contents Information 4. Size(s) of F	Hetail Cont	tainer	5. Location of L		ZIIOL	
Label Container					panying product	
6. Manner In Which Label Is Affixed To Product Lithogr		Othe	r (		)	
Paper Stencil						
Sect	tion IV					
1. Contact Point (Complete items directly below for identification	of individ	ual to be contacted,	if necessary, to	process thi	s application.	
Name	litle			Talaphor.	e No. (Include Area Code)	
Christine A. Dively	Manag	jer				
Jellinek, Schwartz & Connolly, Inc.	Pesti	.cide Registi	rations	(202)	7893323	
Certification					6. Date Application	
I certify that the statements I have made on this form and all at I acknowledge that any knowingly false or misleading statements both under applicable law.	ttachments ent may be	s thereto are true, a e punishable by fine	ccurate and comp or imprisonmen	let <del>s</del> t or	Received (Stamped)	
2. Signature 3						
Elvertine A. Dively		rized Repres Genetics Int				
	. Date					
Christine A. Dively Jellinek, Schwartz & Connolly, Inc.		12, 1994				
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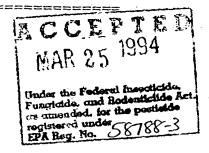
riease read instructions, on reverse detore completing form.

# Fage 1 of 6

# Draft Labelling

### GUSANO™

A Wettable Powder Biological Insecticide for Control of Caterpillars



GUSANO is an IVP (Insecticidal Virus Product) for control of the caterpillars of the insects listed on this label. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

Active Ingredient\*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <u>Autographa californica</u> (alfalfa looper)

3.3%

Inert Ingredients:

96.78

\*This lot contains at least. 10 billion OBs/gr.

Mfg. By: Crop Genetics International

10150 Old Columbia Road Columbia, MD 21046 EPA REGISTRATION No.: 58788-3 ESTABLISHMENT No.: 58788-MD-002

KEEP OUT OF THE REACH OF CHILDREN

### CAUTION

# STATEMENT OF PRACTICAL TREATMENT

In case of contact with eyes flush with plenty of water for at least 15 minutes. If on said, wash thoroughly with soap and water. If inhaled, remove victim to fresh alr. Apply respiration if ladicated. Get medical attention if irritation persists.

### PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: Avoid contact with skin and eyes. This product can cause eye irritation. Wash thoroughly with soap and water after handling. Call a physician if eye irritation persists.

### Page 2 of 6

# Draft Labelling

Personal Protective Equipment: Applicators and other handlers must wear Long-sleeved thirt and long pants
Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

# USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

#### ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment washwaters.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product to a monner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

(Refer to Technical Bulletin for Additional Guidelines for Use.)

#### ACRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains pecific instructions and exceptions pertaining to the statements on this label about personal

protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralls

Waterproof gloves

Shoes plus socks

# GENERAL INFORMATION

GUSANO is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these

Treat when larvae are young (early instars) and are actively feeding on foliage. Apply before extensive foliar damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. GUSANO should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of GUSANO in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

Fill the mix tank with desired quantity of water Agitation should be used during mixing. If a spreader/sticker or ultraviolet screen is used, add prior to the addition of GUSANO. Mixing time can be reduced by premixing GUSANO with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

USE NON-CHLORINATED WATER AT A PH NEAR 7.0 IN THE SPRAY-TANK MIX

### APPLICATION RATES

	Billion OBs per acre	grams per acre
Vegetables Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	100 to 500	<u>5 - 50</u>
Other Crops Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweet- potatoes, tobacco, sunflower, sugarbeets	100 to 500	5 - 50
Silvaculture Trees of various species	100 to 500	<u>5 - 50</u>

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

# Storage

Store this product in a cool, dry place inaccessible to children and pets. Store at temperatures below 90° F. Bioactivity may be impaired by storage above 90° F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may ' disposed of on site or at an approved waste disposal facility. ...sticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL: Plastic container -- triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

Paper container -- completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or if allowed by State and local authorities by burning. If burning is allowed, stay out of smoke.

ITMITED WARRANTY: Crop Genetics International makes no warranty, press or implied including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical

\_\_\_\_\_\_\_

bulletin.

# 

# TECHNICAL BULLETIN GUSANO BIOLOGICAL INSECTICIDE

### PRODUCT DESCRIPTION

GUSANO, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control caterpillars of labelled insect pests.

GUSANO provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

GUSANO is a technical grade lyophilized powder. Its active ingredient is the multicapsid nuclear polyhedrosis virus of the alfalfa looper, Autographa californica.

Active Ingredient\*
Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of Autographa californica (alfalfa looper)

3.3%

Inert Ingredients:

96.7%

\*This lot contains at least 10 billion OBs per gram.

# BIOLOGICAL PROPERTIES

GUSANO belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The OBs are on average about 2  $\mu m$  in size. The virions occluded within the OBs are the infectious units. Virions consist of a variable number of rod-shaped nucleocapsids that are surrounded by an envelops. A nucleocapsid contains a single molecule of covalently closed, circular double stranded DNA of approximately 130,000 base pairs.

The product is rapidly inactivated by temperatures above  $90^{\circ}$  F. For prolonged storage, the product should be kept below  $40^{\circ}$  F.

# Page 5 of 6

# Draft Labelling

TECHNICAL BULLETIN

GUSANO BIOLOGICAL INSECTICIDE

# MODE OF ACTION

The IVP must be ingested to be infective. When infected, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are usceptible.

Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter.

Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of OBs.

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST POLYHEDRA TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

baculoviruses have been found only in invertebrates; no member of this

family is known to infect vertebrates or plants. GUSANO does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International and is to be used at the risk of the user of such information.

Crop Genetics International
10150 Old Columbia Road
Columbia, MD 21046

# AMENDHENT

		* April 1	783/9
·	FAST TRACK 4 APPLICATION FOR AM		· · · · · ·
WITH DATA	Init. Date	NO DATA	Init. Date
FEU		. FEU	J.N. 4-15-94
SIG (DATA)		PM	
FEU			
PM			
	REGULAR APPLICATION FOR AME	NDMENT	
WITH DATA	Init. Date	NO DATA	Init. Date
FEU		FEU	
SIG (DATA)		PM	
PM			

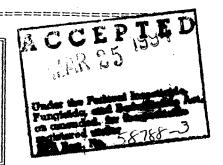
Front End Processing determined this application qualifies for fast track review based on registrants claim of "me-too". No screen for substantial similarity is made by the Front End.

# Page 1 of 6

# Draft Labelling

#### GUSANO™

A Wettable Powder Biological Insecticide for Control of Caterpillars



GUSANO is an IVP (Insecticidal Virus Product) for control of the caterpillars of the insects listed on this label. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

70051-43

Active Ingredient\*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <u>Autographa</u> californica (alfalfa looper)

\_\_\_\_\_\_\_

3.3%

Inert Ingredients:

96.7%

\*This lot contains at least 10 billion OBs/gr.

Mfg. By: Crop Genetics International

10150 Old Columbia Road

Columbia, MD 21046

EPA REGISTRATION NO.: 58788-MD-002

# KEEP OUT OF THE REACH OF CHILDREN

#### CAUTION

# STATEMENT OF PRACTICAL TREATMENT

In case of contact with eyes flush with plenty of water for at least 15 minutes. If on sklu, wash thoroughly with soap and water. If inhaled, remove victim to fresh alr. Apply respiration if inhaled, remove victim to fresh alr.

#### PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: Avoid contact with skin and eyes. This product can cause eye irritation. Wash thoroughly with soap and water after handling. Call a physician if eye irritation persists.

Personal Protective Equipment: Applicators and other handlers must wear Long-sleeved shirt and long pants
Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

### USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

### ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment washwaters.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner laconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

(Refer to Technical Bulletin for Additional Guidelines for Use.)

### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CHR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralls
Waterproof gloves
Shoes plus socks

# GENERAL INFORMATION

GUSANO is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these

Treat when larvae are young (early instars) and are actively feeding on foliage. Apply before extensive foliar damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. GUSANO should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of GUSANO in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

Fill the mix tank with desired quantity of water Agitation should be used during mixing. If a spreader/sticker or ultraviolet screen is used, add prior to the addition of GUSANO. Mixing time can be reduced by premixing GUSANO with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE GPRAY-TANK MIX

#### APPLICATION RATES

	Billion OBs per acre	grams per acre
Vegetables Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	100 to 500	<u>5 - 50</u>
Other Crops Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweet- potatoes, tobacco, sunflower, sugarbeets	100 to 500	<u>5 - 50</u>
Silvaculture Trees of various species	100 to 500	<u>5 - 50</u>

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

# Storage

Store this product in a cool, dry place inaccessible to children and pets. Store at temperatures below 90° F. Bioactivity may be impaired by storage above 90° F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL: Plastic container -- triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

Paper container -- completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or if allowed by State and local authorities by burning. If burning is allowed, stay out of smoke.

IMITED WARRANTY: Crop Genetics International makes no warranty, express or implied including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

# 

# TECHNICAL BULLETIN GUSANO BIOLOGICAL INSECTICIDE

### PRODUCT DESCRIPTION

GUSANO, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control caterpillars of labelled insect pests.

GUSANO provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

GUSANO is a technical grade lyophilized powder. Its active ingredient is the multicapsid nuclear polyhedrosis virus of the alfalfa looper, <u>Autographa californica</u>.

Active Ingredient\*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <u>Autographa californica</u> (alfalfa looper)

3.3%

Inert Ingredients:

96.7%

\*This lot contains at least 10 billion OBs per gram.

# BIOLOGICAL PROPERTIES

GUSANO belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The OBs are on average about 2  $\mu m$  in size. The virions occluded within the OBs are the infectious units. Virions consist of a variable number of rod-shaped nucleocapsids that are surrounded by an envelope. A nucleocapsid contains a single molecule of covalently closed, circular double stranded DNA of approximately 130,000 base pairs.

The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

TECHNICAL BULLETIN

GUSANO BIOLOGICAL INSECTICIDE

### MODE OF ACTION

The IVP must be ingested to be infective. When infected, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible.

Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter.

Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of OBs.

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST POLYHEDRA TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. GUSANO does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International and is to be used at the risk of the user of such information.

Crop Genetics International
10150 Old Columbia Road
Columbia, MD 21046



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

June 12, 1997

Mr. Jow-Li Su, President Thermo Triology Corporation 7500 Grace Drive Columbia, MD 21044

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Dear Mr. Su:

Subject: Transfer of Pesticide Registrations and Data From

Company Number 58788 to Company Number 70051

Pursuant to your request in your letter and transfer agreement undated (received February 10, 1997), we have approved the transfer of the following registrations and data from Crop Genetics International Corporation, company number 58788, to Thermo Triology Corporation, company number 70051.

The effective date of these changes is the date of this letter.

Registered Products	Old EPA Reg. No.	New EPA Reg. No.
SPOD-X Wettable Powder	58788-1	70051-42
Gusano Biological Pesticide	58788-3	70051-43
CYD-X	58788-4	70051-44
GEMSTAR LC	58788-5	70051-45
SPOD-X LC	58788-7	70051-46

You also requested transfer of the Experimental Use Permit, 58788-EUP-1, "INCIDE". According to our records this EUP is inactive and has expired and therefore is not eligible for transfer.

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the

effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer undated (received February 10, 1997) to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date Thermo Triology Corporation will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460-0001

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact me at (703) 305-6474.

Sincerely,

A facke-

Donna G. Parker

Information Management Specialist

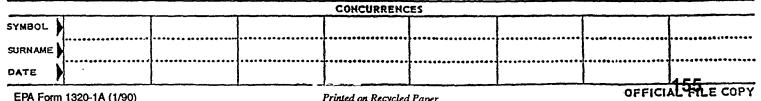
Information Services Branch

Information Resources & Services Div (7504C)

cc: Dr. Edwin C. Quattlebaum, President & CEO Crop Genetics International Corporation 10150 Old Columbia Road Columbia, MD 21046

US ENVIRONMENTAL PROTECTION AGENCY	EPA REGISTRATION NO. DATE OF ISSUANCE
OFFICE OF PESTICIDES PROGRAMS  REGISTRATION DIVISION (TS-767)	58788-3 MAR 25 1994
WASHINGTON, DC 20460	NAME OF PESTICIDE PRODUCT
NOTICE OF PESTICIDE: REGISTRATION .	AMSANO BIOLOGICAL PESTICIDE
(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)	
NAME AND ADDRESS OF REGISTRANT (Include ZIP code)	
Γ-	
Crop Genetics International, Inc 10150 Old Columbia Road Columbia, Maryland 21046	
L.	
NOTE: Changes in labeling formula differing in substance fro submitted to and accepted by the Registration Division prior product always refer to the above U.S. EPA registration number	to use of the label in commerce. In any correspondence on this
In the basis of information furnished by the registrant, the at the Federal Insecticide, Fungicide, and Rodenticide Act.	oove named pesticide is hereby Registered/Reregistered under
A copy of the labeling accepted in connection with this Regis	stration/Reregistration is returned herewith.
•	
FIFRA section 3(c)(5). Once a period is not regarded as permanently a eliminate the need for continual EPA determines, at any time, tha	t additional data are required to registration, the Agency will
label and submit five	Registration No. 58788-3" to the (5) copies of your final printed lease the product for shipment.
A stamped copy of the label	is enclosed for your records.
ATTACHMENT IS APPLICABLE	
SIGNATURE OF APPROVING OFFICIAL	DATE /

### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



EPA Form 1320-1A (1/90)

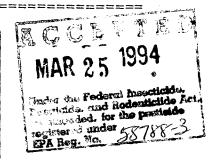
Printed on Recycled Paper

### Page 1 of 6

### Draft Labelling

### **GUSANO™**

A Wettable Powder Biological Insecticide for Control of Caterpillars



GUSANO is an IVP (Insecticidal Virus Product) for control of the caterpillars of the insects listed on this label. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

Active Ingredient\*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <u>Autographa californica</u> (alfalfa looper)

<u>3.3</u>%

Inert Ingredients:

96.7%

\*This lot contains at least 10 billion OBs/gr.

Mfg. By: Crop Genetics International

10150 Old Columbia Road

Columbia, MD 21046

EPA REGISTRATION NO.: 58788-MD-002

### KEEP OUT OF THE REACH OF CHILDREN

### CAUTION

## STATEMENT OF PRACTICAL TREATMENT

In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skla, wash thoroughly with soap and water. If inhaled, remove victim to fresh alr. Apply respiration if Indicated. Get medical attention if irritation persists.

### PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: Avoid contact with skin and eyes. This product can cause eye irritation. Wash thoroughly with soap and water after handling. Call a physician if eye irritation persists.

\_\_\_\_\_\_

Personal Protective Equipment: Applicators and other handlers must wear Long-sleeved shirt and long pauls
Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

### USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

### ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment washwaters.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner laconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

(Refer to Technical Bulletin for Additional Guidelines for Use.)

### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural posticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralls

Waterproof gloves

Shoes plus socks

### GENERAL INFORMATION

GUSANO is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these

Treat when larvae are young (early instars) and are actively feeding on foliage. Apply before extensive foliar damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. GUSANO should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of GUSANO in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

Fill the mix tank with desired quantity of water Agitation should be used during mixing. If a spreader/sticker or ultraviolet screen is used, add prior to the addition of GUSANO. Mixing time can be reduced by premixing GUSANO with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

USE NON-CHLORINATED WATER AT A PH NEAR 7.0 IN THE SPRAY-TANK MIX

### APPLICATION RATES

	<u>Billion</u> OBs per acre	grams per acre
Vegetables Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	100 to 500	<u>5 - 50</u>
Other Crops Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweet- potatoes, tobacco, sunflower, sugarbeets	<u>100 to 500</u>	5 - 50
'Silvaculture Trees of various species	100 to 500	<u>5 - 50</u>

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

### Storage

Store this product in a cool, dry place inaccessible to children and pets. Store at temperatures below 90° F. Bioactivity may be impaired by storage above 90° F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL: Plastic container -- triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

Paper container -- completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or if allowed by State and local authorities by burning. If burning is allowed, stay out of smoke.

LIMITED WARRANTY: Crop Genetics International makes no warranty,

express or implied including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

## TECHNICAL BULLETIN GUSANO BIOLOGICAL INSECTICIDE

### PRODUCT DESCRIPTION

GUSANO, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control caterpillars of labelled insect pests.

GUSANO provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

GUSANO is a technical grade lyophilized powder. Its active ingredient is the multicapsid nuclear polyhedrosis virus of the alfalfa looper, <a href="Autographa californica">Autographa californica</a>.

Active Ingredient\*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <u>Autographa californica</u> (alfalfa looper)

<u>3.3</u>%

Inert Ingredients:

96.7%

\*This lot contains at least 10 billion OBs per gram.

## BIOLOGICAL PROPERTIES

GUSANO belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The OBs are on average about 2  $\mu m$  in size. The virions occluded within the OBs are the infectious units. Virions consist of a variable number of rod-shaped nucleocapsids that are surrounded by an envelope. A nucleocapsid contains a single molecule of covalently closed, circular double stranded DNA of approximately 130,000 base pairs.

The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

### Page 6 of 6

### Draft Labelling

TECHNICAL BULLETIN

GUSANO BIOLOGICAL INSECTICIDE

### MODE OF ACTION

The IVP must be ingested to be infective. When infected, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible.

Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter.

Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of OBs.

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST POLYHEDRA TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. GUSANO does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International and is to be used at the risk of the user of such information.

Crop Genetics International
10150 Old Columbia Road
Columbia, MD 21046

## JELLINEK, SCHWARTZ & CONNOLLY, INC.

To: Linda Hollis

U.S. EPA Document Processing Desk

1921 Jefferson Davis Highway

Crystal Mall II

Arlington, VA 22202

Date: March 24, 1994

Please complete the attached form and give to messenger. Thanks.

40 CFR Part 180

[PP 2F4089/R2036; FRL-4753-2]

RIN 2070-AB78

Polyhedral Occlusion Bodies of Autographa Californica Nuclear Polyhedrosis Virus; Exemption from the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

CTION: Final rule.

**SUMMARY:** This rule establishes an exemption from the requirement of a pesticide olerance for residues of the microbial pest control agent *Autographa californica* nuclear polyhedrosis virus in or on all raw agricultural commodities. The product Gusano is an insecticidal virus product containing the polyhedral occlusion bodies of the naturally occurring *Autographa californica* nuclear polyhedrosis virus (Family: Baculoviridae). This tolerance exemption was requested by Crop Genetics International. This regulation eliminates the need to establish a maximum permissible level for residues of *Autographa californica* nuclear polyhedrosis virus.

**EFFECTIVE DATE:** This regulation becomes effective (insert date of publication in the Federal Register).

JRESSES: Written objections, identified by the document control number, [PP 4089/R2036], may be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing request to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

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EPA Form 1320-1 (12-70)

40 CFR Part 180

[PP 2F4089/R2036; FRL-4753-2]

RIN 2070-AB78

Polyhedral Occlusion Bodies of Autographa Californica Nuclear Polyhedrosis Virus; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

**ACTION:** Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a pesticide obligation. It is rule establishes an exemption from the requirement of a pesticide obligation of the microbial pest control agent Autographa californica nuclear polyhedrosis virus in or on all raw agricultural commodities. The product Gusano is an insecticidal virus product containing the polyhedral occlusion bodies of the naturally occurring Autographa californica nuclear polyhedrosis virus (Family: Baculoviridae). This tolerance exemption was requested by Crop Genetics International. This regulation eliminates the need to establish a maximum permissible level for residues of Autographa californica nuclear polyhedrosis virus.

**EFFECTIVE DATE:** This regulation becomes effective (insert date of publication in the Federal Register).

ADDRESSES: Written objections, identified by the document control number, [PP 2F4089/R2036], may be submitted to: Hearing Clerk (A-110), Environmental rotection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing request to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

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	3K-3588		CONCURRENCES		
SYMBOL	7/04 7/04	75040	1503C		
SURNAME	BHENO GUNTES	CRIVE	Helli		
DATE	2-4-94 2-4-94	2.15/14	2/24/94		

EPA Form 1320-1 (12-70)

40 CFR Part 180

[PP 2F4089/R2036; FRL-4753-2]

RIN 2070-AB78

Polyhedral Occlusion Bodies of Autographa Californica Nuclear Polyhedrosis Virus; Exemption from the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This rule establishes an exemption from the requirement of a pesticide tolerance for residues of the microbial pest control agent *Autographa californica* nuclear polyhedrosis virus in or on all raw agricultural commodities. The product Gusano is an insecticidal virus product containing the polyhedral occlusion bodies of the naturally occurring *Autographa californica* nuclear polyhedrosis virus (Family: Baculoviridae). This tolerance exemption was requested by Crop Genetics International. This regulation eliminates the need to establish a maximum permissible level for residues of *Autographa californica* nuclear polyhedrosis virus.

**EFFECTIVE DATE:** This regulation becomes effective (insert date of publication in the Federal Register).

ADDRESSES: Written objections, identified by the document control number, [PP 2F4089/R2036], may be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing request to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

FOR FURTHER INFORMATION CONTACT: By mail: Phillip O. Hutton, Product Manager (PM) 18, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 207, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-7690.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 10, 1992 (57 FR 24645), EPA issued a notice that it had received PP 2F4089 from Espro, Inc., requesting that 40 CFR part 180 be amended to establish a tolerance for acal (the company and product, renamed "Gusano," have since been acquired

938-3528

by Crop Genetics International, 10150 Old Columbia Rd., Columbia, MD 21046). Gusano contains the polyhedral occlusion bodies of *A. californica* nuclear polyhedrosis virus and is proposed for use in or on all raw agricultural commodities when used to control the alfalfa looper.

No comments were received in response to the notice of filing.

### Residue Chemistry Data

Although Gusano bioinsecticide will be applied on a variety of vegetable and silvaculture crops at rates varying from 5 to 50 grams per acre, residue chemistry data were not required. Such data were determined to be necessary only if the submitted toxicology studies indicate that additional Tier II or III toxicology data would be required as specified in 40 CFR 158.165(e). The submitted toxicology data for this use indicate that the product is of low mammalian toxicity; therefore, Tier II or III data were not required.

### **Toxicology Data**

Toxicology data requirements in support of this exemption from the requirement of a tolerance were satisfied via data waivers from the open scientific literature. These waivers include literature from an acute oral toxicity/ pathogenicity study in the rat, an acute pulmonary toxicity/pathogenicity study in the rat, an acute dermal toxicity study in the rabbit, and a primary eye irritation study in the rabbit. Findings from the open scientific literature showed no toxic, pathogenic, or adverse effects.

Reference Dose (RfD) and maximum permissible intake (MPI) considerations are not relevant to this petition because of the low toxicity and lack of pathogenicity or infectivity as reported in the open scientific literature.

Based on the information cited above, the Agency has determined that the potential acute toxicity/pathogenicity of *Autographa californica* nuclear polyhedrosis virus is sufficiently low to support the proposed exemption from the requirement of a tolerance on all raw agricultural commodities. Thus, a tolerance for the active ingredient *Autographa californica* nuclear polyhedrosis virus is not necessary to protect the public health. Therefore, 40 CFR part 180 is amended as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections and/or request a hearing with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a

reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a "significant regulatory action" as an action that is likely to result in a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations or recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of the Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated:

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

### PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In subpart D, by adding new § 180.1125, to read as follows:

§ 180.1125 Polyhedral occlusion bodies of Autographa californica nuclear polyhedrosis virus; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the microbial pest control agent *Autographa californica* nuclear polyhedrosis virus in or on all raw agricultural commodities.

[FR Doc. 94-????? Filed ??-??-94; 8:45 am]

BILLING CODE 6560-50-F

# **URGENT**

## OFFICE OF PESTICIDES PROGRAM CONCURRENCE AND COMMENT ROUTING SHEET

DATE: 2/3/94

TO:	Addressee indicated below
FROM:	LINISA Hollis RM 209 PM18
TITLE OF	DOCUMENT: Pohy Hedral Occlusion Budies of autographa Californica
nuclea	DOCUMENT: Pohy Hedral Occhision Budies of AutoGrapha Californica r Pohyhedrosis Viker; Exemption from Rewisement of a Tolerance
Pleas	se concur or comment, as indicated, on the attached document. If you do
not concu	or, attach a written explanation of your position. If you have been asked
to commen	nt, attach your comments. Please return this sheet with your comments as A. Hollis by No. 16 your reply is
to LIND	SA A. Hollis by No. 16 your reply is
not recei	ived by that time, we will presume that you concur or have no comment.

Each reviewer who is asked to concur is limited to concurring or non-concurring on matters within his area of expertise as defined by job. Division directors or their designees may concur or non-concur with respect to matters outside their functional area.

	You have b	peen asked to	Divisio	n, Offic	ce or	
			Individ	ual Resp	∞nse	
Division Office	Concur	Comment	Concur	Non	Comment	Signature
or Individual			1	concur	lattached	and Date
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40 CFR Part 180

[PP 2F4089/R2036; FRL-4753-2]

RIN 2070-AB78

Polyhedral Occlusion Bodies of Autographa Californica Nuclear Polyhedrosis Virus; Exemption from the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

OUMMARY: This rule establishes an exemption from the requirement of a pesticide tolerance for residues of the microbial pest control agent *Autographa californica* nuclear polyhedrosis virus in or on all raw agricultural commodities. The product Gusano is an insecticidal virus product containing the polyhedral occlusion bodies of *Autographa californica* nuclear polyhedrosis virus (Family: Baculoviridae). This tolerance exemption was requested by Crop Genetics International. This regulation eliminates the need to establish a maximum permissible level for residues of *Autographa californica* nuclear polyhedrosis virus.

**EFFECTIVE DATE:** This regulation becomes effective (insert date of publication in the Federal Register).

ADDRESSES: Written objections, identified by the document control number, [PP 2F4089/R2036], may be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing request to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

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EPA Form 132	20-1 (12-70)		1	Wicommant	OFFICIAL FILE COPY

## JELLINEK, SCHWARTZ & CONNOLLY, INC.

### **HAND-DELIVERED**

LAID.

Ms. Linda Hollis Product Manager Team 18 Insecticide-Rodenticide Branch Registration Division Office of Pesticide Programs

January 24, 1994

### Dear Linda:

Pursuant to our conversation last week, enclosed please find a revised Confidential Statement of Formula and Data Matrix for Gusano (EPA File Symbol 58788-G). This information is submitted on behalf of Crop Genetics International (7170 Standard Drive Hanover, Maryland 21076).

Please do not hesitate to call me at 202-789-3323 if you have any questions about this submission or any other issues related to the registration of Gusano.

**Enclosures** 

Christine A. Dively -

Christine A. Dively

Jellinek, Schwartz & Connolly, Inc. Authorized Representative of Crop

Genetics International (CGI)

Rev: 12/13/93 3:21pm Printed: 01/25/94 9:39am

## DATA REQUIREMENT LISTING

PRODUCT Gusano	NAME:			NO. OR FILE rmerly 58971)	SYMBOL:	FORMULA	TOR EXEM	PTIO	PTION ASSERTED:						
Crop Geneti 10150 Old C	T'S NAME AND ADDRESS: cs International columbia Road Maryland 21046-1704		APPLICAT 5/31/91	ION DATE:		NAME OF ACTIVE INGREDIENT:  Autographa californica multicapsid nuclear polyhedrosis			1						
DA	TA REQUIREMENTS		SOURCE O	F DATA SATIS	FYING REQU	IREMENT		MRID NUMBER							
Regulation Part 158/ Guideline Number	Name of Test	Submitted by Applicant	Date Submitted	Submitted by another person/firm (name)	Permission letter enclosed	Public literature	N.A. or waiver or other (explain)	EPA ACCESSION NUMBE OR OTHER EPA IDENTIFIYING NUMBER			R,				
151A-10 through 151A-15, 151A-17	Product Chemistry	Х	5/31/91					4	2	0	7	3	0	0	1
151A-16(f)	Analytical Methods Product Chemistry	X	5/31/91				X								
151A-16(g)	Analytical Methods/ Product Chemistry	X	5/31/91				X								
152A-10	Acute Oral Toxicity/Pathogenicity	X	5/31/91				X								
152A-11	Acute Dermal Toxicity	X	5/31/91				X								
152A-12	Acute Pulmonary Toxicity/Pathogenicity	X	5/31/91				X								
152A-14	Primary Eye Irritation	X	5/31/91				X								
152A-15	Hypersensitivity Incidents	X	5/31/91				X								
152A-16	Cell Culture	Х	5/31/91				X								

Rev: 12/13/93 3:21pm Printed: 01/24/94 3:42pm

## DATA REQUIREMENT LISTING

NAME AND ADDRESS: nternational nbia Road land 21046-1704  REQUIREMENTS		APPLICAT: 5/31/91 SOURCE OF	ION DATE:		Autographa	californica		ENT:					1	
		SOURCE OF		NAME OF ACTIVE INGREDIENT: <u>Autographa californica</u> multicapsid nuclear polyhedrosis										
			F DATA SATIS	MRID NUMBER										
nme of Test	Submitted by Applicant	Date Submitted	Submitted by another person/firm (name)	Permission letter enclosed	Public literature	N.A. or waiver or other (explain)	EPA ACCESSION NUMBER, OR OTHER EPA IDENTIFIYING NUMBER			•				
er II, Tier III Toxicity	Х	5/31/91				Х						-		
vian Oral Toxicity	X	5/31/91				X								
eshwater Fish Test	X	5/31/91				х							!	
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JAN 19 1994

James H. Davis
Vice President of Research
and Development
Crop Genetics International
10150 Old Columbia Road
Columbia, Maryland

Subject: GUSANO

EPA File Symbol 58788-G

This correspondence is a pre-acceptance (PA) letter regarding the above cited application. The product referred to above will be acceptable for registration under section 3(c)(5) of FIFRA provided that you do the following:

- 1. In reference to the subject labeling you must:
  - a. Delete "See side panel for precautionary statements"
  - b. Move the signal word "CAUTION" directly centered underneath the Keep Out of Reach of Children statement.
  - c. Delete the subheading "Notice" and replace it with Limited Warranty. Also, move the Limited Warranty statement to the back panel of the label. This should be the last item on the label.
  - d. Under the heading PRECAUTIONARY STATEMENTS delete the signal word "CAUTION". Move the heading "Precautionary Statements" to the front panel of the label directly under the centered signal word "CAUTION". This statement should be revised to read as follows: PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals: Avoid contact with skin and eyes. This product can cause eye irritation.. Wash thoroughly with soap and water after handling. Call a physician if eye irritation persists.
  - e. Delete the Statement "Pesticide, spray mixture ..... approved procedures from the label.

	f.			nt "Do no			• •	
				CONSURRENC	sunder th	ie heading	storage	and
SYMBOL	7505C	Disposa.	•					
SURNAME	Hollis							
DATE	1/12/94				*************			
EDA Como	SPA Form 1220 14 (190) OFFICIAL PLE COPY							

EPA Form 1320-1A (1/90)

- g. Add the heading "Storage" to the label and the following statement: "Store this product in a cool dry area inaccessible to children and pets. Store at temperatures below 90 degrees Fahrenheit. Bioactivity may be impaired by storage above 90 degrees Fahrenheit. Storing this product in a freezer or refrigerator will extend its shelf-life.
- h. Delete the statement "Do not contaminate water by cleaning of equipment or disposal of wastes. However, do add the heading ENVIRONMENTAL HAZARDS to the label and the following statement: "Do not contaminate water when disposing of equipment washwaters".
- i. You have indicated on your application that your product will be packaged in paper and plastic bags (containers), therefore, to your label you must delete the container disposal statement, add the heading "Container Disposal" and the appropriate container disposal language per PR Notice 83-3.
- j. Add the heading "Pesticide Disposal" to the label and the appropriate pesticide disposal language per PR Notice 83-3.
- k. Under the heading "Directions for Use" and below the Federal Misuse Statement, parenthesize the statement "Refer to Technical Bulletin for Additional Guidelines for Use. Directly under this statement, add the subheading "General Information". Provide the buyer with a suggested dilution ratio of water to product.
- 1. Submit a complete data matrix indicating all data submitted and methods of data citation/satisfaction.

Sincerely,

Phil Hutton, PM 18

Insecticide/Rodenticide Branch Registration Division 7505C

CONCURRENCES									
SYMBOL									
SURNAME									
DATE									
EPA Form 1320-1A (1/90)		Printed on Recycled Paper	OFFICIAL PILE COPY						

Form Approved.	OMD No.	2070 0060	Annroyal	ovniroc1	1 20 0
Form Approved.	OMB NO.	2070-0060.	Approvai	i expires i	1-30-9

(A) SEPA United States Environment Office of Pesticide Pro Washington, D Application for	grams (H7505C) C 20460 Amendr	B
Sec	ction I	
Company/Product Number     58788-G	2. EPA Product Manager Phil Hutton	3. Proposed Classification
4. Company/Product (Name)	PM#	X None Restricted
Gusano	18	
5. Name and Address of Applicant (Include ZIP Code)  Crop Genetics International Corporat 10150 Old Columbia Road Columbia, MD 21046  Check if this is a new address	6. Expedited Review. In accorda (b)(i), my product is similar or ident to:  EPA Reg. No  Product Name	ical in composition and labeling
Sect	on I I	
Amendment - Explain below  Resubmission in response to Agency letter dated  Notification - Explain below.	Final printed labels in response to Agency letter dated  "Me Too" Application.  Other - explain below.	0
Explanation: Use additional page(s) if necessary. (For section		
Submission in response to preclearan	ce letter	
Section	n III	
Material This Product Will Be Packaged In:		
Child-Resistant Packaging  Yes*  No  If "Yes,"  No. per	Water Soluble Packaging  Yes  No  If "Yes,"  No per	Metal Plastic Glass Paper Other (Specify)
* Certification must be submitted.	Package wgt. container	
	Retail Container 5. Location of Label	bel Directions
6. Manner In Which Label Is Affixed To Product Paper Stencil	aph Other (	ng accompanying process
Sect	ion IV	
Contact Point (Complete items directly below for identification		
Name James H. Davis	vice riestment	Telephone No. (Include Area Code) (410) 381–3809
Certification I certify that the statements I have made on this form and all at I acknowledge that any knowingly false or misleading statements both under applicable law.	tachments thereto are true, accurate and comple	6. Date Application Pachived (Stamped)
2. Signature 3	Title	
Ye HD-	Vice President	
James H. Davis	December 13, 1993	176

### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any data submitted:
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

 $\overline{ extbf{SECTION}}$  - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned
  to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product
  Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration. Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

<u>SECTION II</u> - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a <u>specific EPA-registered product</u>. This section is <u>not to be</u> used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

<u>SECTION III (Packaging and Container Information)</u> - This Section must be completed for all applications submitted in cornection with not registration or applicable amendments.

- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container 'rdicate type of container in which product will be marketed.
- 3. Location of wet Contends Specify the net contents of all retail containers for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., NEW Braducts registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-expeanatory.
- 6. EPA Use July.

### DATA REQUIREMENTS

## Microbial Pesticides

## Product Analysis

	<u>Guideline</u>	Data Submitted
Product identity Manufacturing process	151A-10 151A-11	MRID Nos. 420730-00; 426408- 01; and 426408-02
Discussion of formation of unintentional ingredients	151A-12	MRID Nos. 420730-00; and 426408-02
Analysis of samples	151A-13	MRID Nos. 420730-00; and 426408-03
Certification of limits	151A-15	MRID Nos. 420730-00; 426408- 03, and 423855-02
Physical and chemical properties	151A-16	MRID Nos. 420730-00; Waiver submitted for 151A-16(f) and 151A-16(g)
Residue Data		
Residue data	153A	Not Required
Toxicology Acute oral toxicity/ pathogenicity	152A-10	Waiver; Acute Intra- peritoneal Toxicity Study submitted, MRID No. 419357-02
Acute dermal toxicity	152A-11	Waiver
Acute pulmonary toxicity/	152A-12	Waiver
Acute intravenous toxicity/ pathogenicity	152A-13	Not Required
Primary eye irritation	152A-14	Waiver
Hypersensitivity incidents	152A-15	Waiver
Cell culture	152 <b>A-</b> 16	Waiver

## <u>Guideline</u>

## Non-Target Organisms and Environmental Expression

Avian oral	154A-16	Waiver
Avian inhalation test	154A-17	Not required
Wild mammal testing	154A-18	Not required
Freshwater fish testing	154A-19	Waiver
Freshwater aquatic invertebrate testing	154A-20	Waiver
Estuarine and marine animal testing	154A-21	Waiver
Nontarget plant studies	154A-22	Waiver
Nontarget insect testing	154A-23	Waiver
Honey bee testing	154A-24	Waiver



## CROP GENETICS INTERNATIONAL

10150 OLD COLUMBIA ROAD COLUMBIA MD 21046-1704 USA TEL 41D 381 3800 FAX 410 381 3840

LAN 13)

December 13, 1993

Philip O. Hutton, PM 18 Registration Division (H7505C) Office of Pesticide Programs Environmental Protection Agency, Room 213 CM #2, 1902 Jefferson Davis Highway Arlington, VA 22202

> Re: GUSANO EPA File Symbol 58788-G Response to Preclearance Letter

Dear Mr. Hutton:

In response to your preclearance letter concerning the GUSANO registration, enclosed are:

- (1) A revised label, and (2) A data waiver: Marky

On the enclosed label, we have not included the Endangered As you ok Species language listed in Paragraph 1(m) of your letter. As you may recall, for our Spod-X Wettable Powder label, the Agency required us to delete the language from our draft label. (See attached letter of May 11, 1993). Accordingly, we have followed  $\psi^{\wedge}$ the same procedure here.

If you have any questions concerning this submission, please do not hesitate to contact me.

Sincerely,

ames H. Davis

vice President of Research & Development

Enclosure

Christine Dively, Jellinek, Schwartz & Connolly, Inc.

US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS 58971-1 MAY 1 1 1993 TERM OF ISSUANCE REGISTRATION DIVISION (75-767) CONDITIONAL WASHINGTON, DC 20460 NAME OF PESTICIDE PRODUCT REGISTRATION NOTICE OF PESTICIDE: SPOD-XIM WETTABLE POWDER (Under the Federal Insecticide, Fungicide, and Rodonilcide Act, as omended) NAME AND ADDRESS OF REGISTRANT (Include ZIP code) \_ 7 CROP GENETICS INTERNATIONAL 7170 Standard Drive Hanover, MD 21076 Ŀ NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number. On the basis of information lumished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act. A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith. Registration is in no way to be construed as an indorsament or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others. This product is conditionally registered in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 3(c)(7)(c) provided that you: Submit/cite all data required for registration/ reregistration of your product under FIFRA section 3(c)(5) or FIFRA section 4 when the Agency requires all registrants of similar products to submit such data. Add the phrase, "EPA Registration No. 58971-1" and Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling. Delete the statement "Open dumping is prohibited. Do not 3. reuse empty containers" from the label as this language is for those products intended for household use. Delete the ENDANGERED LEPIDOPTERAN SPECIES heading from 4. the label and the statement "This product should not be used in close proximity to the areas listed to ensure ATTACHMENT IS APPLICABLE SIGNATURE OF APPROVING OFFICIAL DATE

EPA Form 8570-6 (Rev. 5-76)

PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED. AND COMPANY

that no exposure to the endangered species occurs" as well as the attachment with the listed counties of concern from the label. You should be advised that "In the future, the Agency will require a change in the labeling regarding Endangered Lepidopteran Species whereby a statement must be placed on the label advising that you refer to the County Bulletin.

- 5. Submit a Cell Culture Study within one year of the date stamped on this letter of conditional registration.
- 6. The Technical Bulletin should be separate from the label.
- 7. You must have submitted the required data by May 8, 1994 for the Agency to review.
- 8. This conditional registration will expire automatically on May 9. 1996. If you fail to satisfy the conditions imposed in the registration, EPA may issue a Notice to Cancel the amendment under Section 6(e) of FIFRA.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely yours,

Phil O. Hutton

Product Manager (13)

Insecticide-Roderticide Branch Registration Division (H7505C)

### Page 1 of 6

### Draft Labelling

### GUSANO™

A Wettable Powder Biological Insecticide for Control of Caterpillars

GUSANO is an IVP (Insecticidal Virus Product) for control of the caterpillars of the insects listed on this label. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

Active Ingredient\*
Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of Autographa californica (alfalfa looper)

Inert Ingredients:

\*This lot contains at least 10 billion OBs/gr.

Mfg. By: Crop Genetics International 10150 Old Columbia Road EPA REGISTRATION No.: Columbia, MD 21046 ESTABLISHMENT No.: 58788-MD-002

Net Weight:

Lot No.:

### KEEP OUT OF THE REACH OF CHILDREN

### CAUTION

### PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: Avoid contact with skin and eyes. This product can cause eye irritation. Wash thoroughly with soap and water after handling. Call a physician if eye irritation persists.

### Page 2 of 6

### Draft Labelling

\_\_\_\_\_\_

#### STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Flush eyes with plenty of water. Get medical attention

if irritation persists.

IF ON SKIN: Wash with plenty of soap and water. Get medical

attention if irritation persists.

### ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment washwaters.

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

(Refer to Technical Bulletin for Additional Guidelines for Use)

### GENERAL INFORMATION

GUSANO is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding on foliage. Apply before extensive foliar damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. GUSANO should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of GUSANO in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

### Page 3 of 6

### Draft Labelling

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultraviolet screen is used, add prior to the addition of GUSANO. Mixing time can be reduced by premixing GUSANO with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX

### APPLICATION RATES

	<u>Billion</u> OBs per acre	grams <u>per acre</u>
Vegetables Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	<u>100 to 500</u>	<u>5 - 50</u>
Other Crops Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweet- potatoes, tobacco, sunflower, sugarbeets	100 to 500	<u>5 - 50</u>
Śilvaculture Trees of various species	100 to 500	<u>5 - 50</u>

### **RE-ENTRY**

GUSANO may be applied up to and including the day of harvest and storage.

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

### Storage

Store this product in a cool, dry place inaccessible to children and pets. Store at temperatures below 90° F. Bioactivity may be impaired by storage above 90° F. Storing the product in a freezer or refrigerator will extend its shelf-life.

#### Page 4 of 6

### Draft Labelling

### Pesticide and Container Disposal

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL: Plastic container -- triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

Paper container -- completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or if allowed by State and local authorities by burning. If burning is allowed, stay out of smoke.

LIMITED WARRANTY: Crop Genetics International makes no warranty, express or implied including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

#### Page 5 of 6

#### Draft Labelling

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# TECHNICAL BULLETIN GUSANO BIOLOGICAL INSECTICIDE

#### PRODUCT DESCRIPTION

GUSANO, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control caterpillars of labelled insect pests.

GUSANO provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

GUSANO is a technical grade lyophilized powder. Its active ingredient is the multicapsid nuclear polyhedrosis virus of the alfalfa looper, <a href="https://doi.org/10.1007/journal.com/">https://doi.org/10.1007/journal.com/</a>

Active Ingredient\*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <u>Autographa californica</u> (alfalfa looper)

<u>3.3</u>%

Inert Ingredients:

96.7%

\*This lot contains at least 10 billion OBs per gram.

#### BIOLOGICAL PROPERTIES

GUSANO belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The OBs are on average about 2  $\mu m$  in size. The virions occluded within the OBs are the infectious units. Virions consist of a variable number of rod-shaped nucleocapsids that are surrounded by an envelope. A nucleocapsid contains a single molecule of covalently closed, circular double stranded DNA of approximately 130,000 base pairs.

The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

#### Draft Labelling

# TECHNICAL BULLETIN GUSANO BIOLOGICAL INSECTICIDE

#### MODE OF ACTION

The IVP must be ingested to be infective. When infected, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible.

Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter.

Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of OBs.

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST POLYHEDRA TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. GUSANO does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International and is to be used at the risk of the user of such information.

Crop Genetics International 10150 Old Columbia Road Columbia, MD 21046

### DATA REQUIREMENTS

# Microbial Pesticides

### Product Analysis

	<u>Guideline</u>	Data Submitted	
Product identity Manufacturing process	151A-10 151A-11	MRID Nos. 420730-00; 426408-01; and 426408-02	
Discussion of formation of unintentional ingredients	151A-12	MRID Nos. 420730-00; and 426408-02	
Analysis of samples	151A-13	MRID Nos. 420730-00; and 426408-03	
Certification of limits	151A-15	MRID Nos. 420730-00; 426408-03, and 423855-02	
Physical and chemical properties	151A-16	MRID Nos. 420730-00; Waiver submitted for $151A-16(f)$ and $151A-16(g)$	
Residue Data			
Residue data	153A	Not Required	
Toxicology Acute oral toxicity/ pathogenicity	152A-10	Waiver; Acute Intra- peritoneal Toxicity Study submitted, MRID No. 419357-02	
Acute dermal toxicity	152A-11	Waiver	
Acute pulmonary toxicity/	152A-12	Waiver	
Acute intravenous toxicity/ pathogenicity	152A-13	Not Required	
Primary eye irritation	152A-14	Waiver	
Hypersensitivity incidents	152A-15	Waiver	
Cell culture	152A-16	Waiver	

### <u>Guideline</u>

### Non-Target Organisms and Environmental Expression

Avian oral	154A-16	Waiver
Avian inhalation test	154A-17	Not required
Wild mammal testing	154A-18	Not required
Freshwater fish testing	154 <b>A</b> -19	Waiver
Freshwater aquatic invertebrate testing	154A-20	Waiver
Estuarine and marine animal testing	154A-21	Waiver
Nontarget plant studies	154A-22	Waiver
Nontarget insect testing	154A-23	Waiver
Honey bee testing	154A-24	Waiver

# DATA REQUIREMENTS

### Microbial Pesticides

# Product Analysis

	<u>Guideline</u>	<u>Data Submitted</u>
Product identity	151A-10	MRID Nos. 420730-00; 426408-
Manufacturing process	151A-11	01; and 426408-02
Discussion of formation of	1512 10	WDTD W 420720 001
unintentional ingredients	151A-12	MRID Nos. 420730-00; and 426408-02
Analysis of samples	15 <b>1A-1</b> 3	MRID Nos. 420730-00; and 426408-03
	1513 45	
Certification of limits	1 <b>51A-1</b> 5	MRID Nos. 420730-00; 426408- 03, and 423855-02
Physical and chemical	151A-16	MRID Nos. 420730-00; Waiver
properties		submitted for $151A-16(f)$ and $151A-16(g)$
Residue Data		
Residue data	153A	Not Required
		-
Toxicology '		
Acute oral toxicity/ pathogenicity	152A-10	Waiver; Acute Intra- peritoneal Toxicity Study
pathogenicity	,	submitted, MRID No.
		419357-02
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Acute pulmonary toxicity/	152A-12	Waiver
Acute intravenous toxicity/	152A-13	Not Required
pathogenicity		
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Cell culture	152A-16	/ Waiver

### <u>Guideline</u>

# Non-Target Organisms and Environmental Expression

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### DATA REQUIREMENTS

### Microbial Pesticides

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### DATA REQUIREMENTS

### Microbial Pesticides

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### <u>Guideline</u>

### Non-Target Organisms and Environmental Expression

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Nontarget plant studies	154A-22	Waiver
Nontarget insect testing	154A-23	Waiver
Honey bee testing	154A-24	Waiver



10150 OLD COLUMBIA ROAD COLUMBIA MD 21046-1704 USA TEL 410 381 3800 FAX 410 381 3840

August 26, 1993

Phillip Hutton (H7507C) USEPA Office of Pesticide Programs 401 M Street, S.W. Washington, D.C. 20460

Re: GUSANO, EPA File Symbol 58788-G (previously 58971-G)
Response to your letter of July 28, 1993

Dear Mr. Hutton:

This letter is in response to your letter of July 28, 1993, in which you raised two questions concerning Crop Genetics International's resubmission of January 22, 1993.

- 1. The isolate used in the restriction endonuclease (REN) patterns that were submitted with the January 22, 1993 submission is identical to the isolate that will be used in production of AcMNPV and is the isolate intended for registration.
- 2. With regard to the detection of possible contaminants in the final product, Crop Genetics intends to use the same production control procedures set forth in our recent Cvd-X submission of April 1, 1993.

The protocols for these procedures were submitted in our Cyd-X resubmission of April 1, 1993. See MRID No: 427218-02. These tests will be performed in lieu of the seven bacterial tests originally submitted with the Gusano submission.

If you have any questions concerning this submission, please do not hesitate to contact me.

Sincerely,

James H. Davis

Vice President of Research

and Development



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

NOV 1 9 1993

<u>MEMORANDUM</u>

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SUBJECT:

SAB Consideration of a Petition Requesting an Exemption from the Requirement of a Tolerance for <u>Autographa californica</u> nuclear polyhedrosis virus (DP Barcode D196797; Submission No.: S453494; I.D. No. 2F04089)

TO:

Linda Hollis/Phil Hutton (PM-018) Insecticide-Rodenticide Branch Registration Division (7505C)

FROM:

J. Thomas McClintock, Ph.D., Microbiologist

Biological Pesticide Section

Science Analysis Branch

Health Effects Division (7509C)

THROUGH:

Roy D. Sjoblad, Ph.D., Section Head

Biological Pesticide Section

Science Analysis Branch

Health Effects Division (7509C)

ACTION REQUESTED: Crop Genetics International, Inc. has submitted a request for an exemption from the requirement of a tolerance for Autographa californica nuclear polyhedrosis virus (AcNPV), the active ingredient in GUSANO. SAB received the petition for a tolerance exemption on November 19, 1993.

CONCLUSION: All product identity/characterization and mammalian toxicology data have been submitted and adequately satisfy the requirements as set forth in 40 CFR 158.740. Due to the complete lack of toxicity, pathogenicity and/or infectivity as demonstrated in the mammalian toxicology data base and based on the evaluation of all available data and other relevant information on AcNPV, SAB would recommend an exemption from the requirement of a tolerance.



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

NOV 16 1993

**MEMORANDUM** 

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: SAB Review of Supplemental Information Submitted to

Support the Registration of GUSANO

TO: Linda Hollis/Phil Hutton (PM-018)

Insecticide-Rodenticide Branch Registration Division (7505C)

FROM: J. Thomas McClintock, Ph.D., Microbiologist

Biological Pesticide Section

Science Analysis Branch

Health Effects Division (7509C)

THROUGH: Roy D. Sjoblad, Ph.D., Section Head

Biological Pesticide Section

Science Analysis Branch

Health Effects Division (7509C)

ACTION REQUESTED: Crop Genetics International, Inc. previously submitted supplemental product identity/chemistry data to support the registration of GUSANO, an insecticide containing Autographa californica nuclear polyhedrosis virus (AcNPV) as the active ingredient. During the review the Science Analysis Branch (SAB) of the Health Effects Division (HED) noted two deficiencies: 1) verification that the original PstI restriction profile of the AcNPV isolate was, in fact, the same isolate that CGI intends to use for registration and 2) data on the detection of possible contaminants in the final product; specifically, a description of production control procedures (see May 6, 1993 memorandum from C. Schaffer to L. Hollis/P. Hutton).

In response to a letter sent by the Agency dated July 28, 1993, CGI submitted information (September, 3, 1993) to SAB and the Registration Division addressing each of these deficiencies. SAB has summarized CGI's response below.

<u>DISCUSSION</u>: 1). <u>Verification</u> that the <u>original</u> (see November 12, 1992 memorandum from J. T. McClintock to L. Hollis/P. Hutton) PstI restriction profile of the AcNPV isolate was, in fact, the same isolate that CGI intends to use for registration.

CGI's Response: "The isolate used in the restriction endonuclease (REN) pattern that were submitted with the January 22, 1993 submission is identical to the isolate that will be used in production of AcMNPV and...registration." SAB



NEVER questioned the source of the AcNPV DNA used to generate the REN profiles in the January 22, 1993 submission. SAB was requesting identity of the AcNPV isolate and source of viral DNA used in the <u>ORIGINAL</u> restriction profiles submitted (i.e. AcNPV was compared to several restriction digests of <u>Spodoptera exigua</u> NPV DNA). Based on CGI's latest response, the data submitted in the original submission <u>WILL NOT</u> be used to support the registration of GUSANO. Instead, the data from the January 22, 1993 submission <u>WILL</u> be used to fulfill this data deficiency.

2). Data on the detection of possible contaminants in the final product; specifically, a description of production control procedures.

CGI's Response: CGI intends to use the same production control procedures as set forth in the Cyd-X submission of April 1, 1993 (MRID No. 427218-02).

<u>CONCLUSION</u>: All deficiencies previously noted by SAB have been adequately addressed. All data requirements for HED have been satisfied.

<sup>\*</sup>Manufacturing process information may be entitled to confidential treatment\*

#### August 26, 1993

Phillip Hutton (H7507C) USEPA Office of Pesticide Programs 401 M Street, S.W. Washington, D.C. 20460

Re: GUSANO, EPA File Symbol 58788-G (previously 58971-G)
Response to your letter of July 28, 1993

Dear Mr. Hutton:

This letter is in response to your letter of July 28, 1993, in which you raised two questions concerning Crop Genetics International's resubmission of January 22, 1993.

- 1. The isolate used in the restriction endonuclease (REN) patterns that were submitted with the January 22, 1993 submission is identical to the isolate that will be used in production of AcMNPV and is the isolate intended for registration.
- 2. With regard to the detection of possible contaminants in the final product, Crop Genetics intends to use the same production control procedures set forth in our recont Cyd-X submission of April 1, 1993.

The protocols for these procedures were submitted in our Cyd-X resubmission of April 1, 1993. See MRID No: 427218-02. These tests will be performed in lieu of the seven bacterial tests originally submitted with the Gusano submission.

If you have any questions concerning this submission, please do not hesitate to contact me.

Sincerely,

James H. Davis
Vice President of Research
and Devolopment

\*Manufacturing process information may be entitled to confidential treatment\*



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

#### **MEMORANDUM**

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Subject:

SAB Review of Supplemental Product Identity/Chemistry Data from Crop Genetics International Corporation to Support the Registration of <u>Autographa californica</u> Nuclear Polyhedrosis Virus (Submission No.: S434992; ID No.: 058971-G; DP Barcode No.: D188661).

To:

Phillip Hutton/ Linda Hollis (PM 18) Insecticide-Rodenticide Branch

From:

Cindy Schaffer, Microbiologist Calaber

Biological Pesticides Section

Registration Division (H7505C)

Science Analysis Branch

Health Effects Division (H7509C)

Through:

Roy Sjoblad, Ph.D., Acting Section Head

Biological Pesticides Section

Science Analysis Branch

Health Effects Division (H7509C)

Action:

SAB has been asked to review supplemental product analysis/chemistry data submitted in support of the registration by Crop Genetics International Corporation (CGI) for Gusano, an insecticide containing <u>Autographica californica</u> nuclear polyhedrosis virus (NPV) as the

active ingredient.

<u>Discussion</u>: Since the original submission included only one restriction profile, (PstI) of the NPV DNA, unless CGI states otherwise, SAB is assuming that the source of DNA (i.e. virus strain) for this profile is from the same strain intended for production. Also, the following deficiencies are still outstanding for the product analysis/chemistry package: 1. Data was not provided regarding possible contaminants in the final product that would result in the death of the bioassay insects. 2. A reference which was sited, Martignoni (1978), was not submitted.

DATA EVALUATION REPORT

Reviewed by: Cindy Schaffer, Microbiologist, SAB/HED C Secondary Reviewer: J. Thomas McClintock, Ph.D., Microbiologist,

SAB/HED

STUDY TYPE: Product Analysis Information

MRID NO: 426408-01; 426408-02; 426408-03

TEST MATERIAL: <u>Autographica</u> californica

Nuclear Polyhedrosis

Virus

SYNONYMS: Gusano PROJECT NO: 190IVR

SPONSOR: Crop Genetics International, Hanover, MD TESTING FACILITY: Crop Genetics International, Hanover, MD

TITLE OF REPORT: Restriction Endonuclease Analysis of Gusano,

Autographica Californica Multiply Enveloped

Nuclear Polyhedrosis Virus; Supplement to

Product Chemistry.

AUTHOR(S): Nikolai van Beek, Douglas M. Kolodny-Hirsch

STUDY COMPLETED: 22 January 1993

CONCLUSION: Since the original submission included only

one restriction profile, (PstI) of the NPV DNA, unless CGI states otherwise, SAB is assuming that the DNA source (i.e. virus strain) for this profile is from the same strain intended for production. Also, the following deficiencies are still outstanding for the product analysis /chemistry package:

1. Data was not provided regarding possible contaminants in the final product that would result in the death of the bioassay insects.

2. A reference which was sited, Martignoni

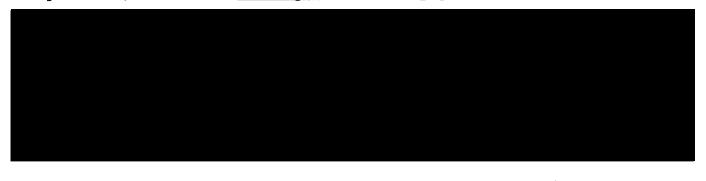
(1978), was not submitted.

NOTE: This material contains CBI

PRODUCT ANALYSIS

151A-10 Product Analysis and Disclosure of Ingredients

Confidential Statement of Formula has been submitted. Gusano contains 3.3% polyhedral occlusion bodies of the nuclear polyhedrosis virus of <u>Autographica californica</u> as the active ingredient; and 96.7% Trichoplusia ni body parts as inerts.





<u>Unintentional Ingredients/Analytical Methods</u>:

**DISCUSSION:** Since the original submission included only one restriction profile, (PstI) of the NPV DNA, unless CGI states otherwise, SAB is assuming that the DNA source (i.e. virus strain) for this profile is from the same strain intended for production. Also, the following deficiencies are still outstanding for the product analysis/chemistry package:

- Data was not provided regarding possible contaminants in the final product that would result in the death of the bioassay insects.
- 2. A reference which was sited, Martignoni (1978), was not submitted.





#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

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NOV 1 2 1992

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

#### MEMORANDUM

SUBJECT: SAB Review of a New Product Registration Application for

GUSANO, a Baculovirus-Based Product (DP Barcode: D172020; Submission No. S407776; MRID Nos. 420730-00, -01, 419357-

02)

TO: Linda Hollis/Phil Hutton

> Insecticide-Rodenticide Branch Registration Division (H7505C)

FROM: J. Thomas McClintock, Ph.D., Microbiologist

Biological Pesticide Section

Science Analysis Branch

Health Effects Division (H7509C)

THROUGH: Roy D. Sjoblad, Ph.D., Acting Section Head

Biological Pesticide Section

Science Analysis Branch

Health Effects Division (H7509C)

ACTION REQUESTED: On behalf of CGI (formerly Espro, Inc.), Jellinek, Schwartz, Connolly and Freshman, Inc. have submitted an application for the registration of GUSANO, an insect virus-based insecticidal product containing the polyhedral inclusion bodies (PIBs) of the multiple-embedded nuclear polyhedrosis virus of californica (AcMNPV), the alfalfa looper. With the exception of certain Product Chemistry studies (i.e. through -15, -17) waivers have been requested for the remaining portion of Series 151A and for all of the toxicology data requirements as outlined in Subdivision M of the Pesticide Assessment Guidelines.

BACKGROUND INFORMATION: Nuclear polyhedrosis viruses classified in the family Baculoviridae, are structurally large and complex DNA-containing viruses infecting insects. Although some NPVs display a specific host range, the NPV of A. californica displays a broad host range infecting over 30 insect species. After ingestion of the virus the occlusion body protein, called polyhedrin, is solubilized by the alkaline conditions of the larval causing the liberation of infectious virions ornucleocapsids from the polyhedral inclusion body The (PIB). attach to the midgut epithelial nucleocapsids cells, transported through the cytoplasm to the nucleus, followed by uncoating of the viral genome and initiation of viral replication. During replication NPVs produce either a single nucleocapsid per envelope (SNPV) or, as is the case with the NPV of  $\underline{A}$ . californica, one to many nucleocapsids per envelope (MNPV) which are occluded in polyhedrin. As the disease progresses infected cells lyse, normal physiological processes are disrupted, the target insect becomes sluggish with the integument rupturing causing death.

<u>CONCLUSIONS/RECOMMENDATIONS</u>: Summarized below is data and information required, but not limited to, for the registration of GUSANO. To fulfill the data requirements for Product Identity/Chemistry the following information and/or data must be submitted:

- 0 Since registrant is using <u>a</u> the single restriction endonuclease (REN) profile to support the product identity requirements a discussion should follow regarding the expected REN patterns of AcMNPV propagated in various hosts and elaborate on any differences (host-induced modifications) which might occur. SAB is also unclear if the AcMNPV isolate used in the REN analysis is the same isolate (or active ingredient) intended for registration. If not, the registrant should provide a REN analysis of their active ingredient for comparison. If the REN profile between the AcMNPV isolates is significantly different then the acceptability of the waiver requests for the mammalian toxicology requirements would be reevaluated.
- O A revised CSF stating that the product contains PIBs of the nuclear polyhedrosis virus of <u>Autographa californica</u> (alfalfa looper) as the active ingredient (see 151A-10 [b]).
- O SAB has focused on assuring lack of contamination with pathogenic toxin-producing microorganisms. Because of the <u>in vivo</u> production method the registrant must (a) specify the specific screens for the detection of significant mammalian pathogens and (b) perform an intraperitoneal injection (10 PIBs/animal) or an acute oral screen (endpoints should include signs of clinical toxicity, mortality) for each independent batch (see 151A-15).
- O Specify QA/QC procedures in place to insure a healthy or disease-free insect colony.

To support the registration of GUSANO the registrant has requested waivers for all acute toxicology requirements. The data and information submitted by the registrant are sufficient to support the waiver request for all toxicology studies since the lyophilized end-use product (EP) which consists solely of AcMNPV PIBs and S. exigua body parts is identical to the technical grade material. Consequently, SAB would not recommend further toxicity testing on the EP.

O <u>152A-15</u>. No cases or incidents of hypersensitivity to AcMNPV have been observed. The applicant <u>must</u> report any incidents of hypersensitivy to the Agency should any incident be observed in the future.

#### SUMMARY OF PRODUCT DATA/INFORMATION

The requirements for Series 151A-10, 151A-11, and 151A-16 have been partially satisfied. The data and information needed to fulfill the requirements for the remaining Series are incomplete.

<u>CLASSIFICATION</u>: Supplementary.

#### SUMMARY OF TOXICOLOGY STUDIES

15/A-10. Acute Oral Toxicity/Pathogenicity. The applicant has requested a waiver for the acute oral toxicity study based, in part, on an acute oral study performed by Hazelton Laboratories (Acute Oral-Rats; Project No. 183-195 AGM; February 21, 1973) using A. californica NPV. Twenty male and 20 female rats were administered by oral intubation 4.35 x10° AcMNPV PIBs/ml and observed for a 21-day period. Several criteria (physical appearance, behavior, clinical studies, organ weights, and gross and microscopic pathology) were used to evaluate compound related effects. No differences were noted, using any of these criteria, between AcMNPV-treated animals and untreated controls.

Oral feeding studies were also performed by Rosner-Hixson Laboratories (Chicago, ILL) using PIBs from  $\underline{S}$ .  $\underline{\text{exigua}}$  and  $\underline{S}$ .  $\underline{\text{frugiperda}}$  NPVs (Laboratory No. 1110-66; November, 11, 1966). In these studies mice were orally dosed with a 1 x 10 PIB suspension in a volume of 0.2 ml. Control animals received 0.2 ml of saline without PIBs. Body weights were recorded weekly and at the end of the two-month study the mice were sacrificed and subjected to necropsy. No differences in body weight gains or significant changes in any of the organs following necropsy were observed between treated and control group animals.

In a third oral feeding study (Carey and Harrap, 1980,  $\underline{In}$  Invertebrate Systems in Vitro) various tissue samples were collected from rats treated with  $\underline{S}$ .  $\underline{littoralis}$  and/or  $\underline{S}$ .  $\underline{exempta}$ , two closely related  $\underline{Spodoptera}$  NPVs, and examined for the presence of virus by giemsa stain. Samples were also assayed for virus by cell culture and bioassay techniques. When samples from treated rats were inoculated into cell culture certain tissues (liver) gave spurious cytopathic effects. However, further evidence failed to substantiate the presence of PIBs. Using giemsa stain, macerates of some gut tissues revealed the presence of polyhedra on Days 0-2, on Day 14 and in one instance on Day 21. These macerates were infectious when fed to  $\underline{S}$ .  $\underline{littoralis}$  larvae.

In a subacute oral study rats were continuously exposed to daily feedings of <u>Spodoptera</u> NPVs for either 45 or 90 days. Smears of tissue macerates from 4 rats (2 males and 2 females) were examined at 45 days and from the remaining rats at 90 days for the presence of polyhedra. No polyhedra were detected in the tissue smears or following cell culture challenge. However, serological testing of sera from treated animals indicated the presence of antibody to <u>Spodoptera</u> particles in a few treated animals. The significance of these observations was not discussed.

Additional data from various feeding studies using different baculoviruses was also submitted to support the registration of GUSANO. In each instance no adverse effects were reported.

<u>CLASSIFICATION</u>: Acceptable. Toxicity Category IV. The data and information submitted are sufficient to satisfy the Acute Oral Toxicity study requirement for the active ingredient.

152A-11. Acute Dermal Toxicity. The applicant has requested a waiver for the acute dermal toxicity study based on an acute dermal toxicity study using A. californica NPV (Hazelton Laboratories, 1972. Primary Skin Irritation in Rabbits, Project No. 183-195) and other NPVs as the test material. Following a single 24-hr application (2.17 x  $10^6$  PIBs/0.5 ml/treatment site) to intact and abraded skin, rabbits were observed for 72 hr and "scored" for adverse effects according to the Draize system. No dermal irritation or treatment-related toxicity was observed during the course of the study.

Additional data/information for dermal studies performed by Rosner-Hixson Laboratories (Chicago, ILL, 1967) were submitted to support the waiver request. Briefly, when applied to abraded skin of guinea pigs both freed virions and PIBs from S. exiqua, S. frugiperda, Heliothis, zea, Trichoplusia ni, and Estigmene acrea at a concentration of 10 to 10 PIBs/mg failed to produce a reaction. Other data/information was submitted which provided further evidence that NPVs do not elicit a response following topical application to the skin.

<u>CLASSIFICATION</u>: Acceptable. Toxicity Category IV. The data are adequate to satisfy the dermal toxicity and dermal irritation requirements for the EP. This study however, is not required for the technical grade active ingredient.

152A-12. Acute Pulmonary Toxicity. The applicant has requested a waiver for this requirement based on studies using the NPV of  $\underline{A}$ . californica as well as other NPVs as the test material. In the primary study (Hazelton Laboratories, Inc., Acute Inhalation Toxicity-Rats, Project No. 183-195, May 18, 1973) rats were exposed to approximately 6 gm of test material for 1 hr and observed for a 14 day period. Several criteria (physical appearance and behavior, body and organ weight, gross and microscopic pathology) were used to evaluate toxicity. Treated rats displayed normal appearance and behavior throughout the course of the study. No treatment-related

toxicity or differences between treated and control groups were observed.

Additional data/information on the effects of different NPVs following pulmonary exposure was provided by the registrant to further support the waiver request. Although procedures and/or details were not provided for some of the referenced articles the results demonstrate a lack of toxicity/infectivity following pulmonary exposure with NPVs.

<u>CLASSIFICATION</u>: Acceptable. Toxicity Category IV. Although the referenced studies were not conducted under current guideline protocols the sum total of the information submitted is sufficient to satisfy the study requirement.

152A-14. Primary Eye Irritation Study. The applicant has requested a waiver for this study based on existing data. In a study performed by Hazelton Laboratories (1972), a single application (0.1 ml) of polyhedra or freed virions (concentrations not provided) from A. californica NPV was introduced into the conjunctival sac of the left eye of rabbits. No signs of eye or conjunctival irritation or corneal damage were noted throughout the course of the study (14 days).

<u>CLASSIFICATION</u>: Acceptable. Toxicity Category IV. The data are adequate to satisfy the primary eye irritation requirements for the EP. This study however, is not required for the technical grade active ingredient.

152A-15. Hypersensitivity Incidents. No cases or incidents of hypersensitivity to AcMNPV have been observed. The applicant must report any incidents of hypersensitivy to the Agency should any be observed in the future. As a note, the active ingredient (AcMNPV PIBs) is not a dermal sensitizer via topical application, but as observed with other NPVs may be a sensitizing agent via intracutaneous injection. Since the dermal route of exposure reflects the topical application route SAB would not recommend that the label contain a "sensitizer" warning.

152A-16. Cell Culture. The applicant has requested a waiver for this study based on existing data from the open literature. extensive literature review of cell culture studies using AcMNPV as the challenge inoculum demonstrated lack of viral replication and infectivity. Using different viral preparations (polyhedra [PIBs], hemolymph from AcMNPV-infected larvae, cell culture medium and cells, and alkali-liberated virions) 23 human cell lines were challenge with AcMNPV. In all instances, AcMNPV uptake occurred; however, once inside the cell viral replication did not occur. Moreover, such studies demonstrated rapid viral DNA degradation and lack of persistence in challenged mammalian cell lines. mammalian information also supports the general lack of toxicity/infectivity of AcMNPV.

CLASSIFICATION: Acceptable.

Reviewed by:

J. Thomas McClintock, Ph.D., Microbiologist

Science Analysis Branch

Health Effects Division (H7509C)

Secondary Review:

Roy D. Sjoblad, Ph.D., Acting Section Head

Science Analysis Branch

Health Effects Division (H7509C)

DATE EVALUATION REPORT

STUDY TYPE: Product Identity

MRID NO.: 420730-00

CASWELL NO.: None Assigned

TEST MATERIAL: Autographa californica multiple-embedded nuclear

polydrosis virus (AcMNPV)

SYNONYMS: GUSANO

STUDY NO.: FR91-12

SPONSOR: CGI (formerly Espro, Inc.)

7170 Standard Drive Hanover, MD 21076

TESTING FACILITIES: University of Florida

Institute of Food and Agricultural Sciences

Entomology and Nematology Department

Gainesville, FLA 32611-0740

TITLE OF REPORT: Product Chemistry

<u>AUTHOR</u>: D. M. Kolodny-Hirsch

REPORT ISSUED: May 31, 1991

<u>CONCLUSION</u>: The requirements for Series 151A-10, 151A-11, and 151A-16 have been partially satisfied. The data and information needed to fulfill the requirements for the remaining Series are incomplete.

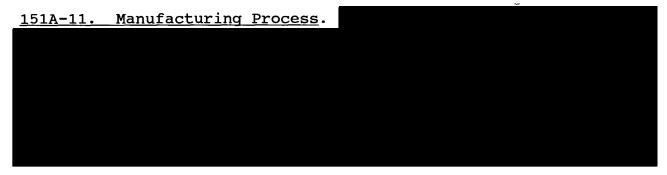
<u>CLASSIFICATION</u>: Supplmentary. This study can be upgraded pending submission of data/information listed below.

151A-10. Product Identity and Disclosure of Ingredients. (a). Product Identity. The active ingredient in GUSANO is the multiple-embedded nuclear polyhedrosis virus of Autographa californica (AcMNPV) which was first isolated and described by Vail et al. (1971). The technical grade material is a lyophilized preparation containing 3% by weight of AcMNPV polyhedral inclusion bodies (PIBs). One reference from the open literature was submitted by

the registrant supporting the identity of the active ingredient (a.i.).



(b). Confidential Statement of Formula (CSF). A CSF was provided by the registrant in support of this application. A revised CSF should be submitted stating that the product contains PIBs of the nuclear polyhedrosis virus of <u>Autographa californica</u> (alfalfa looper) as the a.i. The a.i. (i.e AcMNPV PIBs) and insect components/parts should be considered as the EP.



151A-12. Discussion of Formation of Unintentional Ingredients.

151A-13. Analysis of Samples. The registrant states that "...the fundamental difference of this product from a traditional chemical renders this requirement inappropriate." This rationale is inappropriate, especially in light of the fact that the requirements for Series 151A-12 are inadequate and unacceptable. SAB agrees that analysis and identification of the insect inert components and/or impurities would be impossible; however, the registrant should provide a discussion on the methods and a statement of the precision and accuracy of the method used to analyze each sample or batch for the quantity of PIBs which, in turn, allows for the determination of the certified limits.

151A-15. Certification of Ingredient Limits. A CSF was provided by the registrant stating the certified limits of the a.i. and inerts in GUSANO.

The registrant states that the "procedure for sampling and enumerating polyhedral inclusion bodies of GUSANO are outlined in the article by Martignoni (1978)." This reference may in fact be adequate (reference not found); however this information must be presented and summarized especially if the procedure is modified.

To determine certified limits GUSANO was evaluated and the percent a.i. (PIBs/gm) determined to range from 3% to 10% with an activity titer of no less than "...41 thousand activity units/gram." The number of batches analyzed, the method used for enumeration and/or quantification of the number of PIBs per batch and the data for such calculations were not specified. The determination of the certified limits must be supported by an acceptable analytical method. This data/information should be submitted to the Agency.

The registrant also states that "No fecal coliform bacteria, or any other bacteria or other agents pathogenic for warm-blooded vertebrates are permitted as detected by culturing on differential bacteriological media, by intraperitoneal injection in mice and by oral administration to mice." Again, the registrant implies that specific methodologies are in place to assure QC/QA procedures. SAB recommends that each batch be analyzed by IP injection (10'PIBs/animal) study. The registrant should specify the methods to be used to assure that each batch is void of contaminating pathogens.

151A-16. Physical and Chemical Properties. The following physical and chemical properties were submitted for the end-use product:

<u>Property</u>	<u>Characteristics</u>	
Color	Tan to sandy brown	
Physical State	Solid	
Odor	Humus-like odor	
Density (loose)	0.186 g/cc or	
- , .	11.6 lb/cu. ft.	
(tapped)	0.244 g/cc or	
, <del></del> ,	13.9 lb/cu. ft.	
рН	6.1 using a 4.8% w/w	
-	suspension at 23.5°C	
Viscosity	Not required	
Miscibility	Not required	

Waivers were requested for Stability (151A-16[f]) and Storage Stability (151A-16[g]) studies. The following rationale was provided for each waiver request:

151A-16[f]. Several references were submitted by the registrant to support data waivers for stability. Specifically, various parameters were evaluated for their ability to inactivate both NPVs and GVs (granulosis viruses). One of the most important environmental factors considered was sunlight; whereby inactivation

occurs due to the ultraviolet portion of the spectrum. Information was submitted on pH demonstrating that infectious virions, released from the occlusion bodies, were inactivated at high alkaline (pH 12) and low acidic conditions (pH 1.2). The interaction between temperature and pH was also noted. When virions were suspended in an alkaline solution (pH 11) no inactivation was noted at  $21^{\circ}$ C; however at elevated temperatures ( $40^{\circ}$ C) the infectious virions were inactivated. Further, data from the open literature was presented demonstrating thermal inactivation of baculoviruses at various temperatures.

151A-16[q]. The technical grade of the product, GUSANO, is freezedried, packaged in a vacuum packed bag which is then inserted into a kraft-foil package. The proposed recommended storage is under refrigeration or freezing. In addition to references from the open literature, the registrant submitted raw data on the stability of an analogous product/technical grade material (SPOD-X) subjected to different parameters and/or conditions. Two studies were presented: a long term and an accelerated shelf-life study. The long term study, which is currently in progress, will analyze lyophilized samples (loosely or vacuum packed) stored at  $0\,^{\circ}\text{C}$  and 25°C following 0, 3, 6, 12, and 24 months of storage. accelerated study, lyophilized samples (loosely or vacuum packed) subjected to different storage temperatures (25°C, 37°C, and 45°C) and bioassayed against second-instar S. exiqua larvae, showed no loss in potency for 21 days at 37 °C ( $LC_{50}$  1.3 x 10 PIBs/ml), but a ten-fold increase in the  $LC_{50}$  after 3 days at 45°C ( $LC_{50}$  1.0 x 10° PIBs/ml). The remaining data or a portion thereof, which was not submitted, will be shared between the two trials. The results from these two trials should be submitted to the Agency upon completion.

009848

J. Thomas McClintock, Ph.D., Microbiologist Reviewed by:

Science Analysis Branch

Health Effects Division (H7509C)

Secondary Review: Roy D. Sjoblad, Ph.D., Acting Section Head

Science Analysis Branch

Health Effects Division (H7509C)

DATE EVALUATION REPORT

STUDY TYPE: Acute Intraperitoneal Toxicity Study

MRID NO.: 419357-02 CASWELL NO.: None

Assigned

TEST MATERIAL: Autographa californica multiple-embedded nuclear

polydrosis virus (AcMNPV)

SYNONYMS: **GUSANO** 

**STUDY NO.:** S3197

SPONSOR: CGI (formerly Espro, Inc.)

7170 Standard Drive Hanover, MD 21076

TESTING FACILITIES: Cosmopolitan Safety Evaluations, Inc.

P. O. Box 71

Lafayette, NJ 07848

Acute Intraperitoneal Toxicity/Pathogenicity TITLE OF REPORT:

in Mice Dosed with Acal

Geoffrey Robbins AUTHOR:

REPORT ISSUED: June 18, 1991

An intraperitoneal injection of approximately 1x10' PIBs/animal (0.385 mg/0.5 ml) of A. californica NPV did not produce any apparent signs of overt systemic toxicity following a 21-day test period.

CLASSIFICATION: Acceptable.

STUDY DESIGN: A. Test Article. The test article consisted of PIBs of A. californica NPV (Lot No. 050191). The test article was diluted into 0.5 ml sterile normal saline to a concentration of 1x10' PIBs/animal which was equivalent to 0.385 mg/0.5 ml/animal).

Test Animal. Young adult mice (AAI Mice, NIH) with weights ranging from 19.0 to 21.8 gm were used.

C. <u>Methods</u>. Twenty-nine male and 29 female mice were divided into 3 test groups which consisted of a control group (3 male and 3 female-no injection), a treated group (14 male and 14 female-0.385 mg of test substance/animal), and a vehicle control group (12 male and 12 female-0.5 ml sterile normal saline). Body weights were recorded prior to dosing and on Day 3, Day 7, Day 14, Day 21 and at death. Upon termination of the study all animals were sacrificed and the following organs examined: heart, lungs, spleen, liver, adrenals, kidneys, urinary bladder, stomach, small and large intestines, and reproductive organs. Body fluid and tissue were harvested for quantification of the microbial test article. Urine and feces were also collected for microbial quantification.

RESULTS: All treated and control group mice survived to the scheduled sacrifice date. There was no evidence of treatment-related signs following administration of the test material and throughout the course of the study. All treated animals exhibited normal body weight gain throughout the course of the study.

<u>DISCUSSION</u>: An intraperitoneal injection of approximately 1x10<sup>7</sup> PIBs/animal of <u>A</u>. <u>californica</u> NPV did not produce any apparent signs of overt systemic toxicity following a 21-day test period.

#### ADMINISTRATIVE MATERIAL

### Resubmission in Response to January 4, 1993 Letter

Volume Number

I

EPA's File Symbol

58971-G

Crop Genetics International 7170 Standard Drive Hanover, MD 21076

(410) 712-7170



# **Crop Genetics International**

7170 Srandard Drive • Hanover, Maryland 21076-1334 USA (410) 712-7170 • TELEFAX (410) 712-0104

January 21, 1993

Mr. Phillip Hutton
Document Processing Desk (BIOTECH)
Office of Pesticide Programs-H7504C
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

Dear Mr. Hutton:

Your letter of 4 January 1993 described certain deficiencies in the Product Identity/Chemistry data requirements as submitted under FIFRA for new product registration of Gusano, <u>Autographa californica</u> nuclear polyhedrosis virus (EPA File Symbol 58971-G). In response to your review of the above application, we are submitting or resubmitting the following:

#### Vol. I - Administrative Materials

- Application for pesticide registration (EPA Form 8570-1).
- A revised CSF (EPA Form 8570-4) stating that the product contains polyhedral occlusion bodies of the nuclear polyhedrosis virus of <u>Autographa californica</u> (alfalfa looper) as the active ingredient.
- A revised product label.

#### Vol. II - Product Identity/Chemistry

• A recently completed study (CGI Study No. 190IVR) which provides identifying restriction endonuclease patterns of the product strain of Gusano propagated from the specified production host <u>Trichoplusia</u> <u>ni</u> (cabbage looper).

Mr. Phillip Hutton January 22, 1993 Page -2-

### Vol. III - Product Identity/Chemistry

- A revised Manufacturing Process (151A-11) which now includes a description of procedures to insure a healthy production insect colony.
- A revised Discussion of Formation of Unintentional Ingredients (151A-12) which describes the specific tests to be used to detect fecal coliforms and mammalian pathogens or toxins. Note that the microbial assay methods cited from Martignoni (1978) are no longer used in this section.

### <u>Vol. IV</u> - Product Identity/Chemistry

- A revised Analysis of Samples (151A-13).
- A revised Certification of Ingredient Limits (151A-15) incorporating data from recent Gusano production lots and including a detailed description of the quantification methods used for occlusion body concentration.

Also, please note that the completed storage stability studies requested in your letter of January 4, 1993 have previously been supplied in our resubmission of the Spod-X application (EPA File Symbol 58971-R), Vol. III, Guideline 151A-16g, MRID #42385502.

Furthermore, CGI will take appropriate steps to insure that this product is not used in close proximity to those areas identified by EPA as containing endangered species.

Sincerely,

James H. Davis

Please read instructions on reverse before completing for	rm. Form	Approved. OMB No. 20	070-0060. Approval expires 11-30-93
(A) United States Environme	ental Protection Agency	Registra	ODD 1 de effere Norther
Office of Pesticide F Washington, Application		Amendm	
Application	for Pesticide:	<b>x</b> Other	100102
	Section I		
Company/Product Number	2. EPA Product I	Manager	3. Proposed Classification
58971-G	Phil Hu	atton	
Company/Product (Name)	PM#		None Restricted
Gusano	18		
5. Name and Address of Applicant (Include ZIP Code)			nce with FIFRA Section 3(c)(3)
Crop Genetics International	(b)(i), my produ to:	act is similar or identic	cal in composition and labeling
7170 Standard Drive Hanover, MD 21076			
	EPA Reg. No		
Check if this is a new address	Product Name_		
Se	ction I I		
Amendment - Explain below		ed labels in response to	
Resubmission in response to Agency letter dated 1/4/	/93	Application.	
Notification - Explain below.	Other - exp	plain below.	
Explanation: Use additional page(s) if necessary. (For section	on I and Section II.)		
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MAS	** ***		
1. Material This Product Will Be Packaged in:	tion III		<u> </u>
Child-Resistant Packaging Unit Packaging	Water Soluble Packaging	2. Type of Co	ontainer
Yes* Yes	Yes	N	Metal /
l	▼ No	1 1 1 1 1 1 1	Plastic <sup>®</sup> Glass
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Se	ction IV		
1. Contact Point (Complete items directly below for identification	T	1-	
Name Christine A. Dively	Title Manager, Pest	.TCTGC	elephone No. (Include Area Code)
Jellinek, Schwartz & Connolly, Inc.	Registrations	,	202-789 -3323
Certification	on .		6. Date Application
I certify that the statements I have made on this form and all	attachments thereto are true	, accurate and complete	e. ReceiveJ
I acknowledge that any knowingly false or misleading states both under applicable law.	ment may be punishable by	fine or imprisonment or	(Stamped)
2. Signature	3. Title		
		lent of Researc	h
Clanes HD-	and Develop	ment	1 224

#### Page 1 of 5

#### Draft Labelling

<b>=========</b> ===========================	=======================================	:===========	==============

GUSANO A Wettable Powder Biological Insecticide for Control of the Caterpillars

GUSANO is an IVP (Insecticidal Virus Product) for control of the caterpillars of the insects listed on this label. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

#### KEEP OUT OF THE REACH OF CHILDREN

See additional precautionary statements and statements of practical treatment on the side panel.

Active Ingredient\*

Polyhedral occlusion bodies (OBs) of Autographa californica (alfalfa looper) nuclear polyhedrosis virus

3.3%

Inert Ingredients:

96.78

\*This lot contains at least 10 billion OBs/gr.

Crop Genetics International makes no warranty, express or implied including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

Mfq. By: Crop Genetics International

7170 Standard Drive

EPA REGISTRATION No.: Hanover, MD 21076 ESTABLISHMENT No.: 58783-MD-001

Net Weight:	Lot No.:	-

#### Page 2 of 5

#### Draft Labelling

## 

#### PRECAUTIONARY STATEMENTS

#### CAUTION

Hazards to Humans: This product can cause eye irritation. Avoid contact with skin and eyes. Wash thoroughly with soap and water after handling. Call a physician if eye irritation persists.

Do not contaminate water by cleaning of equipment or disposal of wastes.

\_\_\_\_\_\_

#### STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Flush eyes with plenty of water. Get medical attention if irritation persists.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

#### DIRECTIONS FOR USE.

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Refer to Technical Bulletin for Additional Guidelines for Use.

GUSANO is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding on foliage. Apply before extensive foliar damage has occurred. When insect infestations are heavy use the higher label rates.

Thorough spray coverage is essential for good insect control. GUSANO should be applied by conventional application equipment with quantities of water to provide thorough coverage of infested plants without runoff.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultra-

#### Page 3 of 5

#### Draft Labelling

violet screen is used, add prior to the addition of GUSANO. Mixing time can be reduced by premixing GUSANO with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX

#### APPLICATION RATES

	<u>Billion</u> OBs per acre	grams <u>per acre</u>
Vegetables Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	<u>100 to 500</u>	<u>5 - 50</u>
Other Crops Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweet- potatoes, tobacco, sunflower, sugarbeets	100 to 500	<u>5 - 50</u>
Silvaculture Trees of various species	100 to 500	<u>5 – 50</u>

#### RE-ENTRY

GUSANO may be applied up to and including the day of harvest and storage.

#### STORAGE AND DISPOSAL

Bioactivity may be impaired by storage above 90° Fahrenheit. Storing the product in a freezer or refrigerator will extend its shelf-life.

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.

Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with federal and local regulations. Containers should be triple-rinsed and disposed of in an approved landfill or incinerated. Consult Federal, State or local disposal authorities for approved procedures.

#### Page 4 of 5

#### Draft Labelling

## 

## TECHNICAL BULLETIN GUSANO BIOLOGICAL INSECTICIDE

#### PRODUCT DESCRIPTION

GUSANO, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control caterpillars of labelled insect pests.

GUSANO provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

GUSANO is a technical grade lyophilized powder. Its active ingredient is the multicapsid nuclear polyhedrosis virus of the alfalfa looper, Autographa californica.

Active Ingredient\*

Polyhedral occlusion bodies (OBs) of the alfalfa looper nuclear polyhedrosis virus

3.3%

Inert Ingredients:

96.7%

\*This lot contains at least 10 billion OBs per gram.

#### BIOLOGICAL PROPERTIES

GUSANO belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The OBs are on average about 2 µm in size. The virions occluded within the OBs are the infectious units. Virions consist of a variable number of rod-shaped nucleocapsids that are surrounded by an envelope. A nucleocapsid contains a single molecule of covalently ciosed, circular double stranded DNA of approximately 130,000 base pairs.

The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

#### Page 5 of 5

#### Draft Labelling

TECHNICAL BULLETIN

## GUSANO BIOLOGICAL INSECTICIDE

#### MODE OF ACTION

The IVP must be ingested to be infective. When infected, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible.

Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter.

Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of OBs.

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST POLYHEDRA TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. GUSANO does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

\_\_\_\_\_\_\_

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International and is to be used at the risk of the user of such information.

Crop Genetics International 7170 Standard Drive Hanover, MD 21076

### ADMINISTRATIVE MATERIAL

## Resubmission in Response to January 4, 1993 Letter

Volume Number

I

EPA's File Symbol

58971-G

Crop Genetics International 7170 Standard Drive Hanover, MD 21076

(410) 712-7170



## **Crop Genetics International**

7170 Srandard Drive • Hanover, Maryland 21076-1334 USA (410) 712-7170 • TELEFAX (410) 712-0104

January 21, 1993

Mr. Phillip Hutton
Document Processing Desk (BIOTECH)
Office of Pesticide Programs-H7504C
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

Dear Mr. Hutton:

Your letter of 4 January 1993 described certain deficiencies in the Product Identity/Chemistry data requirements as submitted under FIFRA for new product registration of Gusano, <u>Autographa californica</u> nuclear polyhedrosis virus (EPA File Symbol 58971-G). In response to your review of the above application, we are submitting or resubmitting the following:

#### Vol. I - Administrative Materials

- Application for pesticide registration (EPA Form 8570-1).
- A revised CSF (EPA Form 8570-4) stating that the product contains polyhedral occlusion bodies of the nuclear polyhedrosis virus of <u>Autographa californica</u> (alfalfa looper) as the active ingredient.
- A revised product label.

#### Vol. II - Product Identity/Chemistry

 A recently completed study (CGI Study No. 190IVR) which provides identifying restriction endonuclease patterns of the product strain of Gusano propagated from the specified production host <u>Trichoplusia</u> <u>ni</u> (cabbage looper). Mr. Phillip Hutton January 22, 1993 Page -2-

### Vol. III - Product Identity/Chemistry

- A revised Manufacturing Process (151A-11) which now includes a description of procedures to insure a healthy production insect colony.
- A revised Discussion of Formation of Unintentional Ingredients (151A-12) which describes the specific tests to be used to detect fecal coliforms and mammalian pathogens or toxins. Note that the microbial assay methods cited from Martignoni (1978) are no longer used in this section.

### Vol. IV - Product Identity/Chemistry

- A revised Analysis of Samples (151A-13).
- A revised Certification of Ingredient Limits (151A-15) incorporating data from recent Gusano production lots and including a detailed description of the quantification methods used for occlusion body concentration.

Also, please note that the completed storage stability studies requested in your letter of January 4, 1993 have previously been supplied in our resubmission of the Spod-X application (EPA File Symbol 58971-R), Vol. III, Guideline 151A-16g, MRID #42385502.

Furthermore, CGI will take appropriate steps to insure that this product is not used in close proximity to those areas identified by EPA as containing endangered species.

Sincerely,

James H. Davis



Please read instructions on reverse before completing for	mForm Approved, OMB No. 2	2070-0060. Approval expires 11-30-93
(A) SEPA United States Environment Office of Pesticide Programment Washington, Application	ntal Protection Agency Registra	ation OPP Identifier Number
	ection I	
Company/Product Number     58971-G	2. EPA Product Manager Phil Hutton	3. Proposed Classification
Company/Product (Name)	PM#	None Restricted
Gusano	18	
5. Name and Address of Applicant (Include ZIP Code)  Crop Genetics International 7170 Standard Drive Hanover, MD 21076  Check if this is a new address	6. Expedited Review. In accorda (b)(i), my product is similar or ident to:  EPA Reg. No  Product Name	tical in composition and labeling
Sec	tion i i	
Amendment - Explain below	Final printed labels in response t Agency letter dated	0
Resubmission in response to Agency letter dated 1/4/9	"Me Too" Application.	
Notification - Explain below.	Other - explain below.	
O-all		
Section 1 Material This Product Will Be Prokaged in	on III	
Material This Product Will Be Packaged In:     Child-Resistant Packaging Unit Packaging	Water Soluble Packaging 2. Type of	Container
Yes*  No  If "Yes,"  No. per	Yes	Metal Plastic Glass Paper
* Certification must be Unit Package wgt. container submitted. N/A	Package wgt. container N/A	Other (Specify)
	Retail Container  5. Location of La  The container on Label  On Labeli	bel Directions ng accompanying product
6. Manner In Which Label Is Affixed To Product    Lithog   Paper	graph Other ( r glued Other (	)
Sec  1. Contact Point (Complete items directly below for identification	ction IV on of individual to be contacted, if necessary, to pr	rocess this application.)
Name Christine A. Dively	Tide Manager, Pesticide	Telephone No. (Include Area Code)
Jellinek, Schwartz & Connolly, Inc.	Registrations	202-789-3323
Certification I certify that the statements I have made on this form and all a I acknowledge that any knowingly false or misleading statem both under applicable law.	attachments thereto are true, accurate and comple nent may be punishable by fine or imprisonment of	6. Date Application Received or (Stamped)
2. Signature  Janes HD	3. Title Vice President of Resear and Development	232

### Page 1 of 5

#### Draft Labelling

=======================================	===========	 ==========	:======

GUSANO
A Wettable Powder
Biological Insecticide
for Control of the
Caterpillars

GUSANO is an IVP (Insecticidal Virus Product) for control of the caterpillars of the insects listed on this label. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

## KEEP OUT OF THE REACH OF CHILDREN

KEEP OUT OF THE REACH OF CHILDREN	
CAUTION: See additional precautionary statements and practical treatment on the side panel.	statements of
=======================================	:========
Active Ingredient* Polyhedral occlusion bodies (OBs) of	
<u>Autographa californica</u> (alfalfa looper) nuclear polyhedrosis virus	3.3%
Inert Ingredients:	<u>96.7</u> %

\*This lot contains at least 10 billion OBs/gr.

NOTICE: Crop Genetics International makes no warranty, express or implied including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

Mfg. By: Crop Genetics International
7170 Standard Drive EPA REGISTRATION No.:
Hanover, MD 21076 ESTABLISHMENT No.: 58788-MD-001

Net Weight: Lot No.:\_\_\_\_\_

\_\_\_\_\_\_\_

#### Page 2 of 5

### Draft Labelling

## PRECAUTIONARY STATEMENTS

#### COLO I DILLIAM

#### CAUTION

Hazards to Humans: This product can cause eye irritation. Avoid contact with skin and eyes. Wash thoroughly with soap and water after handling. Call a physician if eye irritation persists.

Do not contaminate water by cleaning of equipment or disposal of wastes.

\_\_\_\_\_\_

#### STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Flush eyes with plenty of water. Get medical attention if irritation persists.

#### DIRECTIONS FOR USE.

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Refer to Technical Bulletin for Additional Guidelines for Use.

GUSANO is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding on foliage. Apply before extensive foliar damage has occurred. When insect infestations are heavy use the higher label rates.

Thorough spray coverage is essential for good insect control. GUSANO should be applied by conventional application equipment with quantities of water to provide thorough coverage of infested plants without runoff.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultra-

#### Page 3 of 5

#### Draft Labelling

violet screen is used, add prior to the addition of GUSANO. Mixing time can be reduced by premixing GUSANO with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

# USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX

APPLICATION RATES

### Billion grams OBs per acre per acre Vegetables 100 to 500 5 - 50 Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion Other Crops 100 to 500 5 - 50 Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets Silvaculture 100 to 500 Trees of various species

## RE-ENTRY

GUSANO may be applied up to and including the day of harvest and storage.

#### STORAGE AND DISPOSAL

Bioactivity may be impaired by storage above  $90^{\circ}$  Fahrenheit. Storing the product in a freezer or refrigerator will extend its shelf-life.

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.

Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with federal and local regulations. Containers should be triple-rinsed and disposed of in an approved landfill or incinerated. Consult Federal, State or local disposal authorities for approved procedures.

#### Page 4 of 5

### Draft Labelling

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## TECHNICAL BULLETIN GUSANO BIOLOGICAL INSECTICIDE

#### PRODUCT DESCRIPTION

GUSANO, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control caterpillars of labelled insect pests.

GUSANO provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

GUSANO is a technical grade lyophilized powder. Its active ingredient is the multicapsid nuclear polyhedrosis virus of the alfalfa looper, <a href="Autographa californica">Autographa californica</a>.

Active Ingredient\*

Polyhedral occlusion bodies (OBs) of the alfalfa looper nuclear polyhedrosis virus

3.3%

Inert Ingredients:

96.7%

\*This lot contains at least 10 billion OBs per gram.

#### BIOLOGICAL PROPERTIES

GUSANO belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The OBs are on average about 2  $\mu m$  in size. The virions occluded within the OBs are the infectious units. Virions consist of a variable number of rod-shaped nucleocapsids that are surrounded by an envelope. A nucleocapsid contains a single molecule of covalently closed, circular double stranded DNA of approximately 130,000 base paics.

The product is rapidly inactivated by temperatures above 90° f. For prolonged storage, the product should be kept below 40° F.

### Page 5 of 5

#### Draft Labelling

## TECHNICAL BULLETIN GUSANO BIOLOGICAL INSECTICIDE

#### MODE OF ACTION

The IVP must be ingested to be infective. When infected, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible.

Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter.

Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of OBs.

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST POLYHEDRA TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

\_\_\_\_\_\_\_

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. GUSANO does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International and is to be used at the risk of the user of such information.

Crop Genetics International 7170 Standard Drive Hanover, MD 21076

	DATE: 1-41-93.
TO:	FILE ROOM
	DOCUMENT CENTER S/G
	PRODUCT MANAGER/8
	PAM (ROOM 263)
FROM:	2 minus
TYPE (	OF REGISTRATION
	FAST - TRACK ACTION (with data/without data)
	This action has been determined to be a fast-track action by FEPS and $\underline{\text{must}}$ be entered in the PRATS using one of the following codes:
	160 - Application for "me-to" registration
	170 - Application for registration - old chemical - "Me- too" with additional use.
	300 - Amendment - label revision - administrative (no data required).
	305 - Amendment - label revision - data required does not need HED/EFED review.
	<pre>310 - Amendment - added "me-too" Use - no HED/EFED review    needed.</pre>
	345 - Formula change - no HED/EFED review required.
I	REGULAR REGISTRATION (with data/without data)
2	24C NEW
2	24C AMENDMENT
V	RESUBMISSION (response to Agency ltr)
1	FINAL PRINTED LABELS
(	OTHER
MPGGA	GE:



## **Crop Genetics International**

7170 Standard Drive • Hanover, Maryland 21076-1334 USA (410) 712-7170 • TELEFAX (410) 712-0104

January 21, 1993

Mr. Phillip Hutton
Document Processing Desk (BIOTECH)
Office of Pesticide Programs-H7504C
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

Dear Mr. Hutton:

Your letter of 4 January 1993 described certain deficiencies in the Product Identity/Chemistry data requirements as submitted under FIFRA for new product registration of Gusano, <u>Autographa californica</u> nuclear polyhedrosis virus (EPA File Symbol 58971-G). In response to your review of the above application, we are submitting or resubmitting the following:

#### Vol. I - Administrative Materials

- Application for pesticide registration (EPA Form 8570-1).
- A revised CSF (EPA Form 8570-4) stating that the product contains polyhedral occlusion bodies of the nuclear polyhedrosis virus of <u>Autographa californica</u> (alfalfa looper) as the active ingredient.
- A revised product label.

## Vol. II - Product Identity/Chemistry

4264080 • A recently completed study (CGI Study No. 190IVR) which provides identifying restriction endonuclease patterns of the product strain of Gusano propagated from the specified production host Trichoplusia ni (cabbage looper).

Mr. Phillip Hutton January 22, 1993 Page -2-

## Vol. III - Product Identity/Chemistry

- 42640802 A revised Manufacturing Process (151A-11) which now includes a description of procedures to insure a healthy production insect colony.
  - A revised Discussion of Formation of Unintentional Ingredients (151A-12) which describes the specific tests to be used to detect fecal coliforms and mammalian pathogens or toxins. Note that the microbial assay methods cited from Martignoni (1978) are no longer used in this section.

<u>Vol. IV</u> - Product Identity/Chemistry

- 426408\$\psi 3 A revised Analysis of Samples (151A-13).
  - A revised Certification of Ingredient Limits (151A-15) incorporating data from recent Gusano production lots and including a detailed description of the quantification methods used for occlusion body concentration.

Also, please note that the completed storage stability studies requested in your letter of January 4, 1993 have previously been supplied in our resubmission of the Spod-X application (EPA File Symbol 58971-R), Vol. III, Guideline 151A-16g, MRID #42385502.

Furthermore, CGI will take appropriate steps to insure that this product is not used in close proximity to those areas identified by EPA as containing endangered species.

Sincerely,

Aames H. Davis

160 429325 25 13 JAN 14 1998

Christine A. Dively Jellinek, Schwartz, Connolly & Freshman, Inc. 1015 15th Street N.W. Suite 500 Washington, DC 20005

Subject: Gusano - <u>Autographa</u> <u>californica</u> nuclear polyhedrosis virus

EPA File Symbol 58971-G

Response to Review

Dear Mrs. Dively:

The submission referred to above, submitted in connection with registration under FIFRA, as amended is unacceptable at this time. The following deficiencies and/or data gaps must be met before this product can be reviewed any further.

## I. Product Identity/Chemistry Data Requirements

- provide a detailed discussion regarding the expected restriction endonuclease (REN) patterns of AcMNPV propagated in various host, elaborating on any differences which might occur. Provide information indicating whether or not the AcMNPV isolate used in the REN analysis is the same isolate to be used for registration. In the event that the isolates are different, provide a REN analysis of the active ingredient. You should be advised that a significant difference between the AcMNPV isolates may result in a reevaluation of the mammalian toxicology waiver requests.
- clarify the derivation of the viral preparation used in the REN analysis. Submit a revised CSF stating that the product contains PIBs of the nuclear polyhedrosis virus of <u>Autographa californica</u> (alfalfa looper) as the active ingredient. This statement along with "insect parts" should also be placed on the label under the heading "Ingredients Statement".
- provide data regarding the type of other contaminants which would result in the death of the bioassay insects.

CONCURRENCES						
SYMBOL 17505C			****			
SURNAME Hollis						
DATE 1-4-93			,			
EDA Form 1220 1A (1700)		Duinted on Donated	n	· · · · · · · · · · · · · · · · · · ·	OFFIC	4.1FILE COPY

- provide information regarding the specific test(s) used for detection, identification and enumeration of microbial contaminants for the seven types of bacteria that you have listed.
- provide the methods/protocols and specify the specific screens for the detection of significant mammalian pathogens. Perform an intraperitoneal injection (10° PIBs/animal) or an acute oral screen (endpoints should included signs of clinical toxicity, mortality) for each independent batch.
- provide a discussion of the Analytical Method used as well as a statement of the precision and accuracy of this method. The number of batches analyzed, the method used for enumeration and/or quantification of the number of PIBs per batch and the data for such calculations have not been specified. would allow for the determination of the certified limits.
- provide the Agency with the reference cited Martignoni (1978) and submit a summary of the "procedure for sampling and enumerating polyhedral inclusions bodies of GUSANO.
- specify that QC/QA procedures are in place to ensure a healthy or disease-free insect colony.
- upon completion, submit the results from the storage stability studies.

#### Endangered Species Considerations

use of GUSANO insecticide in Washington, California and Florida may affect endangered Lepidopteran The specific locations of the endangered insect species. species in these areas can be found in the attachment. product should not be used in close proximity to these areas to ensure that no exposure to the endangered species occurs.

This application will be kept open for a period of 75 days to give you an opportunity to correct the deficiencies listed above. If you find that you need more time to satisfy the requirements, you should request an extension and commit yourself to satisfy the deficiencies within a reasonable state period of time. not comply with this procedure, the Agency may administratively withdraw your application from further consideration, and retire this file without further notice to you in accordance with the policy established by PR Notice 75-4 of August 27, 1975. Once this

CONCURRENCES						
SYMBOL H7505C						
SURNAME Hollis						
DATE 1-4-93						
EPA Form 1320-1A (1/90)		Printed or	Recycled Paper		OFFICI	242ILE COPY

EPA Form 1320-1A (1/90)

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

3

is done, you will have to submit a complete new application should you wish to pursue the registration of your product after the application has been withdrawn.

If you have any questions regarding this matter, please feel free to contact Linda A. Hollis of my staff @ (703) 305-6397.

Sincerely yours,

Philip O. Hutton, PM 18

Insecticide/Rodenticide Branch Registration Division H7505C

ATTACHMENTS

	CONCURRENCES							
SYMBOL )	H7505C							
SURNAME	Hollis			·				
DATE	1-4-93							

EPA Form 1320-1A (1/90)

OFFICI**PURILE COPY** 

## 407776, 429325 SUBMISSION NO.

128885	
SHAUGHNESSEY	NO.

1

REVIEW NO.

## EEB REVIEW

DATE: IN	12-5-91 OUT NOV 17 1992	
	058971-G	
DATE OF SUBMISSION	7-9-91	·
DATE RECEIVED BY EFED	12-5-91	
RD REQUESTED COMPLETI	ON DATE12-19-92	
	ION DATE	
RD ACTION CODE/TYPE O	F REVIEWO1O	
DATA ACCESSION NO(S). PRODUCT MANAGER NO	D, H, F, N, R, S <u>Microbial</u> Linda Hollis/P. Hutton (PM-1)  utographa Californica NPV	18)
	Espro, Inc.	
- PORMISSION PURPOSE	Section 3 Registration	
	HEMICAL pha californica NPV	% FORMULATION

#### EEB REVIEW

<u>Pesticide Name</u>: Autographa californica Nuclear Polyhedrosis Virus

#### 100.0.0 Submission Purpose and Label Information

#### 100.1.0 Submission Purpose and Pesticide Use

Espro, Inc. has requested a Section 3 Registration for Gusano which contains Autographa californica a multicapsid nuclear polyhedrosis virus. The product is active against a number of caterpillars on the following crops: vegetable and cole crops; field crops; and trees of various species.

#### 100.2.0 Formulation Information

#### Wetable Powder Biological insecticide

ACTIVE INGREDIENT

Polyhedral inclusion bodies (PIBs) of the alfalfa looper nuclear polyhedrosis virus.....3.5%

Inert Ingredients.......96.5%

TOTAL

This lot contains at least 10 billion PIB and 1 million beet activity units (AUs) per gram.

## 100.3.0 Application Methods, Directions, Rates

Gusano is a highly selective insecticide for use against caterpillars on the following crops using the listed rates:

	Million <u>Aus/acre</u>	grams <u>/acre</u>
Vegetables Tomatoes, lettuce cabbage, beans, peppers, celery, escarole, sweet-corn peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	10-50	10-50
Other Crops Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	10-50	10-50
Silvaculture Trees of various species	10-50	10~50

Gusano should be mixed with non-chlorinated water (near Ph 7.0) at the labeled rates and agitation should be used during mixing. The final formulation should be mixed for 10-30 minutes before use. Treatment should be made when

the insect larvae are young (early instars) and are actively feeding on foliage. If insect infestations are heavy, the higher label rates should be used. A spreader/sticker and ultraviolet screening agent may be needed to enhance the performance of this product.

#### 100.4.0 Target Organisms

alfalfa looper, beet armyworm, black cutworm, bollworm, cabbage looper, celery looper, corn earworm, cotton leafperforator, diamondback moth, douglass fir tussock moth, eastern tent caterpillar, elm spanworm, european corn borer, fall armyworm, fall cankerworm. fall webworm, imported cabbageworm, orangestriped oakworm, pink bollworm, saltmarsh caterpillar, southwestern corn borer, soybean looper, tobacco budworm, tomato fruitworm, white cutworm

#### 100.5.0 Precautionary Labeling

The label contains the following precautions:

KEEP OUT OF REACH OF CHILDREN

CAUTION: See additional precautionary statements and statements of practical treatment on the side panel

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS): (adequate)

ENVIRONMENTAL HAZARD STATEMENT: Do not contaminate water by cleaning equipment or disposing of wastes.

(Pesticide and container disposal directions are adequate)

#### 101.0.0 <u>Hazard Assessment</u>

### 101.1.0 <u>Discussion</u>

The nuclear polyhedrosis virus used as the a.i. in this product is Autographa californica isolated from the alfalfa looper. The registrant has addressed each of the requirements for this type of product by supplying data from studies found in the open literature. This data will be used to justify waivers for each of these requirements.

A review of the studies submitted for this product demonstrated that no significant risk to nontarget wildlife should be expected from exposure of this product at the proposed use rates.

## 101.2.0 Likelihood at Adverse Effects to Nontarget Organisms

#### Avian Studies

No avian studies using this particular virus have been cited in the literature, however, studies using other NPVs have been reported. Spodoptera litura was fed to chicks (1.5x10 PIBs dosage) with no effect on behavior, temperature, weight gain, or feed conversion ratio. The gypsy moth NPV has been shown to have no effect on caged quail and several species of free-living birds tested in the wild. Twelve different NPVs have been tested on a number of bird species with no adverse effects being reported. Therefore no adverse effects to birds are expected from the use of Gusano.

#### Fish Studies

Several tests have been conducted testing the effect of NPVs on fish including this one. Rainbow trout and sunfish were exposed to 10 and 10 polyhedra/gal of Autographa californica NPV and no mortality was observed. White suckers and trout were fed spruce budworm NPV at 10' polyhedra/gm body weight and no mortality or virus replication in the fish tissues was observed. Salmon and trout were exposed to Douglas-fir tussock moth NPV by injection, by adding the virus to their water, and by inoculating cell cultures (10 units/ml) with no evidence of toxicity or infection. The gypsy moth NPV did not adversely effect bluegill or brown trout, challenge by Neodiprion lecontei NPV (106 PIBs/g body weight per os) did not produce a response in rainbow trout, Mamestra brassicae NPV was shown to pass harmlessly through the alimentary tract of trout after feeding, and spruce budworm NPV was shown not to interfere with a cytopathogenic virus or infect a minnow cell line. Reports in the literature which tested Autographa californica in addition to other NPVs indicate that this NPV does not cause adverse effects to fish.

#### Mammalian Wildlife

These studies are required only when toxicology data are inadequate for assessment of hazard to wild mammals. The available toxicology data indicates that risk to wild mammals from the proposed uses of Gusano insecticide is minimal.

#### Aquatic Invertebrate Studies

A literature search was conducted and no studies were found testing the effect of Autographa californica NPV on aquatic invertebrates. However, there were studies testing the effect of other NPVs on aquatic invertebrates. N. lecontei NPV did not produce any Daphnid mortality or brood size changes after 14 days with a dose of 2.4x10 PIBs/ml. The virus was not found in any of the fish tissue sectioned at the end of the study. Gypsy moth NPV had no effect on Daphnia, Chironomus, or Notonecta, and H. zea NPV had no effect on Daphnia. Based on these studies and the fact that aquatic invertebrates have frequent exposure to NPVs in nature with no documented adverse effects, Autographa californica NPV should not have any adverse on aquatic invertebrates.

#### Estuarine and Marine Animal Studies

A search of the literature uncovered two studies using Autographa californica NPV and shrimp. White and brown shrimp injected with 10 virus rods or fed a diet containing up to 8000 polyhedra/ul of food produced no indication of virus toxicity or pathogenicity upon gross observations or examination of various shrimp tissue. The estuarine grass shrimp Palaemontes after being feed food pellets containing 10 polyhedra/pellet showed no differences in mortality or behavior between the treated and control shrimp after 30 days. The shrimp showed no evidence of virus infection, viral replication or cytopathogenic activity. From the results of these studies, Autographa californica should not cause adverse effects on estuarine and marine animals.

#### Nontarget Plant Studies

The NPVs are unique among the described viruses and are not biochemically or morphologically similar to plant viruses. To our knowledge, there are no reports in the literature of Baculoviruses (which includes this virus) as being toxic or pathogenic to plants or plants being affected in any way by these viruses. In view of this information, no nontarget plant hazard is expected from the proposed uses of Gusano insecticide.

#### Honey Bee Studies

A review of the literature demonstrated that Autographa californica NPV had been tested on honey bee. A review of 6 publications contained in a literature review of the baculoviruses showed that NPVs from 6 lepidoptera larvae

(Autographa californica, Choristomeura fuiferana, Heliothis zea, Mamertra brassicae, Thymelicus lineola, and Neodiprion lecontei) were tested on honeybees and did not show any abnormalities or deleterious effects in egg production, brood rearing, worker and queen mortality, and general colony behavior. In addition, the NPVs S. frugipeda, Heliothis zea, Trichoplusia ni, Lymantria dispar, Hemerocampa (Orygia) pseudotsugata, and Neodiprion sertifer had been fed to honey bees (Aphis mellifera) in observation hives at a dose of 1x10 polyhedra/200 ml of 50% sucrose solution. No differences were observed between treated and control colonies. From these results, it appears to the best of our knowledge that NPVs such as Autographa californica should not cause adverse effects to honey bees.

#### Nontarget Beneficial Insect Studies

There are a number of literature citations concerning NPV testing on predators and parasites. The reports indicate that there does not seem to be an effect on predators (pentatomids, lacewings, ladybirds and scavenger beetles) that consume NPV infected larvae. Parasites also do not seem to be directly affected by NPVs. NPV infected Spodoptera litura larvae did not alter the development of the parasite Parasarchopaga misera and NPV infection in the lawn armyworm, Spodoptera maruitia, did not seem to affect parasitization by the solitary internal larval parasite, Apanteles marginiventris. However, the parasites host may die prematurely which would cause the larvae not to develop. This should only occur when the larvae are infected at an early stage (later infection would allow the parasites to develop) and generally the parasites tend to avoid parasitizing diseased larvae. From these results, it does not appear to the best of our knowledge that NPVs will cause adverse effects to predatory or beneficial insects.

#### 101.3.0 Endangered Species Considerations

This product may be expected to be used throughout the United States with possible exposure to all endangered/threatened species that are susceptible to this virus. Based on the toxicity and exposure data, EEB feels that there will not be a "may affect" situation for endangered mammals, birds, non-lepidopteran invertebrates, plants and aquatic species.

The use of Guano insecticide in Washington, Oregon, California and Florida, however, may affect endangered lepidopteran insect species. Based on information available to EEB, the following are counties in which the

use of this product may result in hazard to endangered/threatened species of lepidopterans:

#### County, State

#### Los Angeles, CA

Contra Costa, CA Mendocino, CA San Francisco, CA San Mateo, CA

Monterey, CA
Kern, CA
Dade, FL
Monore, FL
Lane, OR
Pacific, WA
Tillamook, WA

#### Species of Concern

El Segundo blue butterfly
Palos Verdes blue butterfly
Lange's metalmark butterfly
Lotis blue butterfly
Mission blue butterfly
Mission blue butterfly
San Bruno elfin butterfly
Smith's blue butterfly
Kern primrose sphinx moth
Schaus swallowtail butterfly
Oregon silverspot butterfly
Oregon silverspot butterfly
Oregon silverspot butterfly

 In California the species and specific areas to be avoided are as follows:

Lotis blue butterfly - Mendocino County - 3 miles south of Mendocino City to Fort Bragg along a 2 mile corridor along Highway 1.

Lange's metalmark butterfly - Contra Costa County - Antioch Sand Dunes Wildlife Refuge.

Mission blue butterfly and San Bruno elfin butterfly - San Mateo County - San Bruno Mountain, Milgara Ridge, Skyline College (Guadalupe Canyon Parkway), Sweeney Ridge, and Montana Mountain.

Smith's blue butterfly - Monterey County - Seaside Marina coastal dune complex from the City of Monterey to Point Gorda, Fort Ord Military Reservation, Seaside Dunes, California Department of Fish and Game preserve near the mouth of the Salinas River, Monterey Sand Hills, Lobos State Preserve, Partington Canyon between Highway 1 and Partington Cove, Burns Creek, several west-facing canyons adjacent to Highway 1 between Malpaso and Garrapatacreeks, north-facing slopes adjacent to Carmel River between Boronda and Paso Hondo roads near Carmel Valley, Vasquez Knob, and Paraiso springs.

El Sequndo blue butterfly - Los Angeles County - International Airport and Chevron Refinery.

Kern primrose sphinx moth - Kern County - Walker Basin

- 2. In Florida, the insect virus, or any formulations thereof, should not be used in the Dade County Keys in Key Biscayne national Park, thence southward to Lower Metacumbe Key in Monroe County
- 3. The insect virus, or any formulations thereof, should not be near the Pacific Ocean in Tillamook County, Oregon and Pacific County, Washington, where the Oregon silverspot butterfly is known to occur.

The registrant will need to ensure that the use of this product does not cause a hazard to these endangered/ threatened species. Guano should not be applied near any of the habitats of these insects. If the product is to be used in any of the listed counties, the applicator should avoid the specific areas containing these insect habitats.

#### 101.4.0 Adequacy of Toxicity Data

(See the Generic Data Table)

The registrant has addressed the data requirements outlined in the Pesticide Assessment Guidelines, Subdivision M.

Generic Data Requirements For Gusano

Data Requirements	Test' Substance	Use <sup>2</sup> Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?
§158.740 Microbial Pes	ticide Nontar	get Organis	m - Tier I		
Avian Testing					
154-16 Avian Acute Ora	ι				
- bobwhite quail	TGAI	A,B,G	No		No <sup>4</sup>
- mallard duck	TGAI	A,B,G	No		No <sup>4</sup>
Aquatic Organism Testi	<u>ng</u>				
154-19 Freshwater Fish	LC50				
- rainbow trout	TGAI	A,B,G	No		No <sup>4</sup>
154-20 Freshwater Invertebrate					
- <u>Daphnia magna</u>	TGAI	A,B,G	No		No <sup>4</sup>
154-21 Estuarine and M	larine				
- animals	TGAI	A,B,G	No		No <sup>3</sup>

#### Additional Testing

154-22 Nontarget plant studies

	- selected species	TGAI	A,B,G	No	 No <sup>4</sup>
154-23	Nontarget insect tes	ting			
	- beneficials	TGAI	A,B,G	No	 No <sup>4</sup>
154-24	Honey bee testing				
	- adult bees	TGAI	A,B,G	No	 No <sup>4</sup>

<sup>1/</sup> TGAI = Technical Grade of the Active Ingredient; TEP = Typical End-Use Product.

#### 101.5.0 Adequacy of Labeling

The precautionary labeling (see sec. 100.5.0) is adequate and no additions/modifications need to be made.

Endangered Species Labeling: Endangered species labeling is deferred until the Technical Bulletin information is made available by OPP.

#### 102.0.0 Classification: N/A

### 103.0.0 Conclusions

EEB has reviewed the proposed Section 3 Registration of Gusano by Espro, Inc. for control of several insect species on vegetables, cole crops, field crops, and various tree species. The studies submitted by the registrant do not specifically address the testing requirements but can be used to grant waivers for each of the requirements. EEB concludes that risk to nontarget wildlife from the proposed uses of Gusano will be minimal to nonexistent.

#### Endangered species considerations

The use of Gusano insecticide in Washington, Oregon, California and Florida may affect endangered Lepidopteran insect species. The specific locations of the endangered species in these areas are listed in section 101.3.0.

<sup>2/</sup> The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G= Forestry; H= Domestic, Outdoor; I = Indoor.

<sup>3/</sup> Only required if there will be exposure to the estuarine and marine environment (e.g. turf use)

<sup>4/</sup> The registrant submitted studies from the open literature that demonstrated a lack of adverse effects to the nontarget organisms in each testing category and the testing was waived.

Counties in which the use of this product may result in hazard to endangered/threatened species of Lepidopterans

#### County, State

#### Los Angeles, CA

Contra Costa, CA Mendocino, CA San Francisco, CA San Mateo, CA

Monterey, CA
Kern, CA
Dade, FL
Monore, FL
Lane, OR
Pacific, WA
Tillamook, WA

#### Species of Concern

El Segundo blue butterfly
Palos Verdes blue butterfly
Lange's metalmark butterfly
Lotis blue butterfly
Mission blue butterfly
San Bruno elfin butterfly
Smith's blue butterfly
Kern primrose sphinx moth
Schaus swallowtail butterfly
Schaus swallowtail butterfly
Oregon silverspot butterfly
Oregon silverspot butterfly

1. In California the species and specific areas to be avoided are as follows:

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Lange's metalmark butterfly - Contra Costa County - Antioch Sand Dunes Wildlife Refuge.

Mission blue butterfly and San Bruno elfin butterfly - San Mateo County - San Bruno Mountain, Milgara Ridge, Skyline College (Guadalupe Canyon Parkway), Sweeney Ridge, and Montana Mountain.

Smith's blue butterfly - Monterey County - Seaside Marina coastal dune complex from the City of Monterey to Point Gorda, Fort Ord Military Reservation, Seaside Dunes, California Department of Fish and Game preserve near the mouth of the Salinas River, Monterey Sand Hills, Lobos State Preserve, Partington Canyon between Highway 1 and Partington Cove, Burns Creek, several west-facing canyons adjacent to Highway 1 between Malpaso and Garrapatacreeks, north-facing slopes adjacent to Carmel River between Boronda and Paso Hondo roads near Carmel Valley, Vasquez Knob, and Paraiso springs.

El Sequndo blue butterfly - Los Angeles County - International Airport and Chevron Refinery.

Kern primrose sphinx moth - Kern County - Walker Basin

- 2. In Florida, the insect virus, or any formulations thereof, should not be used in the Dade County Keys in Key Biscayne national Park, thence southward to Lower Metacumbe Key in Monroe County
- 3. The insect virus, or any formulations thereof, should not be near the Pacific Ocean in Tillamook County, Oregon and Pacific County, Washington, where the Oregon silverspot butterfly is known to occur.

The registrant will need to ensure that the use of this product does not cause a hazard to these endangered/ threatened species. Guano should not be applied near any of the habitats of these insects. If the product is to be used in any of the listed counties, the applicator should avoid the specific areas containing these insect habitats.

128885 SHAUGHNESSEY NO.

REVIEW NO.

## EEB REVIEW

DATE: IN <u>12-5-91</u>	OUT	_
FILE OR REG. NO	058971 <b>-</b> G	
PETITION OR EXP. NO.		
DATE OF SUBMISSION	7-9-91	·
DATE RECEIVED BY EFED	12-5-91	
RD REQUESTED COMPLETION DATE	12-19-92	
EEB ESTIMATED COMPLETION DATE	I	
RD ACTION CODE/TYPE OF REVIEW	010	
TYPE PRODUCT(S) : I, D, H, F,	N, R, S <u>Microbial</u>	
DATA ACCESSION NO(S).		
PRODUCT MANAGER NOLinda	Hollis/P. Hutton (PM-18	)
PRODUCT NAME(S) <u>Autograph</u>	na Californica NPV	
COMPANY NAMEEspr	o, Inc.	
SUBMISSION PURPOSE <u>Section</u>	n 3 Registration	
·		
SHAUGH. NO. CHEMICAL	\$	FORMULATION
128885 Autographa cali	ifornica NPV	3.5
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## **SEPA**

United States Environmental Protection Agency Washington, DC 20460

# Certification with Respect to Citation of Data

Form Approved OMB No. 2070-0060 Approval expires 9-30-90

Applicant's Name and Address	EPA File Symbol/Registration Number			
Espro, Inc.				
Oakland Center	58971- G			
8980 Route 108	Product Name			
Columbia, MD 21045				
	Gusano			
	Date of Application			
	May 31, 1991			

- 1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product or of any other product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application.
- 2. I certify that, for each study cited in support of this application for registration that is an exclusive use study, I am the original data submitter, or have obtained the written permission of the original data submitter to cite that study.
- 3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

I am the original data submitter; or I have obtained the written permission of the original data submitter to cite that study; or

I have notified in writing the companies who have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act; and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

active ingroption un Statement	npanies who have submitted the st	te-all method or cite-all he General Offer to Pay
Signature /	Name and Title	Date
Mr Gila	Aldis E. Adamson	
113 Ch	Vice President	May 31 1991
	ay: I hereby offer and agree to pay	-

persons, with regard to the approval of this application, to the extent required by FIFRA sec. 3(c)(1)(D) and 3(c)(2)(D).

Name and Title
Aldis E. Adamson
Vice President

Page 1991

Way 31, 1991

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## JELUNEK, SCHWARTZ, CONNOLLY & FRESHMAN, INC.

1015 15th Street, N.W., Suite 500 Washington, D.C. 20005

Telephone (202) 789-8181 Fax (202) 789-8243 / 789-8244

May 31, 1991

Mr. Philip O. Hutton
Product Manger (18)
Insecticide-Rodenticide Branch
Registration Division (H7505C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: GUSANO, EPA File Symbol 58971Request for an Exemption From the Requirement of a Tolerance

#### Dear Phil:

On behalf of Espro, Inc. (Oakland Center, 8980 Route 108, Columbia, Maryland 21045), I am requesting an exemption from the requirement of a tolerance for the baculovirus product, GUSANO (Autographa californica).

The name, chemical identity, and composition of GUSANO, as well as the label and supporting data (waiver requests), are submitted with this exemption request. A copy of the request to waive the tolerance exemption fee (original to Mr. Donald Stubbs) along with a copy of a certified check for #1300 is enclosed with this letter.

Please do not hesitate to call me if you have any questions about the tolerance exemption request or the application for pesticide registration for GUSANO.

Sincerely yours,

Christine A. Wirely

Jellinek, Schwartz, Connolly

& Freshman, Inc.

Authorized Representative of Espro, Inc.

#### Enclosures

CC: Donald Stubbs, Acting Branch Chief/ Registration Support Branch



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		Section I				
1. Company/Product Number	<del> </del>	سرت سيكسيك	. EPA Product Ma	nager	3	B. Proposed Classification
Espro, Inc./589			Phil Hutton			·
4. Company/Product (Name		P	M#			X None Restricted
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Espro, Inc./Gusa			18			
<ol><li>Name and Address of Ap</li></ol>	plicant (Include ZIP Code)		•			with FIFRA Section 3(c)(3)
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Columbia, MD 2	1045					
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NameChristine A.		Title	1		Teler	phone No. (Include Area Code)
Jellinek, Schwa	rtz, Connolly &		, Pesticide			202) 789–3323
Freshman, Inc.		Registr	ations			
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I certify that the statement	ts I have made on this form and	all attachments	thereto are true, a	occurate and	d complete.	1
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May 31, 1991

Aldis E. Adamson EPA Form 8570-1 (Rev. 12-90)

Previous editions are obsolete.

White - FPA File Conv (original)

260 Yellow - Annlicant conv

#### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

<u>INSTRUCTIONS</u>: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned
  to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product
  Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

<u>SECTION II</u> - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a <u>specific EPA-registered product</u>. This section is <u>not to be</u> used for a new application for registration.

1. Subject of s:/mission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential scatement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

<u>SECTION III (Packaging and Container Information)</u> - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of Packaging Cheak the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Content: Specify the net contents of all retail containers for your product.
- 4. Size(s) or Retail Container Specify the net contents of all retail containers for your product.
- 5. Location or Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions,

- i.e., new products registration, resubmission, "me-too," reregistration, etc.
- 1-5. Self-explanatory.
  - 6. EPA Use Only.

# U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

ESPRO, INC. 8980 OAKLAND CENTER ROUTE 108 COLUMBIA, MD 21045

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 10/21/91. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be substantially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exception(s) noted below. A copy of your bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents, and correct the noted exception(s) in future data submittals. If deficiencies were found which apply to your overall submission, they are described following this paragraph. If the deficiencies apply to specific studies, they are listed below following the applicable identification number or MRID. Thank you for your cooperation. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

#### MRID 42073001:

Only one statement of confidentiality is necessary for a study, including any supplemental data or appendices which accompany the study.

William and the same

-500

## JELUNEK, SCHWARTZ, CONNOLLY & FRESHMAN, INC.

Telephone (202) 789-8181 Fax (202) 789-8243 / 789-8244

May 31, 1991

Mr. Phillip O. Hutton
Product Manager (18)
Insecticide-Rodenticide Branch
Registration Division (H7505C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: New Product Registration Application for GUSANO EPA File Symbol 58971-

#### Dear Phil:

On behalf of Espro, Inc. (8980 Oakland Center, Route 108, Columbia, Maryland 21045), I am respectfully submitting an application for pesticide registration and other information to support the registration of GUSANO (Autographa Californica multicapsid nuclear polyhedrosis virus). The following materials are included in the submittal package:

Section	Volume	Guideline #	Study Title
	I	NA	Administrative Materials
A	IIA	151A-10 through 151A-15, 151A-17	Product Chemistry 42073001
	IIB	151A-16(f)	Waiver $\triangle DMIN_{o}$
	IIC	151A-16(g)	Waiver
В	I	N/A	Label (in Administrative Vatoriels)

Secti <b>on</b>	Volume	Guideline #	Study Title
C .	III	152A-10	Request for ADMI/ Waiver-Acute Oral Toxicity/Pathogenicity
	IA	152A-11	Request for Waiver- Acute Dermal Toxicity
	V	152A-12	Request for Waiver-Acute Pulmonary Toxicity/ Pathogenicity
	VI	152A-14	Request for Waiver—Primary Eye Irritation
į.	VII	152 <b>A-1</b> 5	Request for Waiver-Hypersensitivity Incidents
	VIII	152A-16	Request for Waiver-Cell Culture
	IX		Request for Waiver-Tier II, Tier III Toxicity Studies
	Х	154A-16	Request for Waiver—Avian Oral Toxicity
	XI	154A-19	Request for Waiver-Freshwater Fish Test
	XII	154A-20	Request for Waiver-Freshwater Aquatic Invertebrate
			Test
	XIII	154A-21	Request for
	XI	154A-22	Request for Waiver-Nontarget Plant tudies

Section	Volume	Guideline #	Study Title	
	xv	154A-23	Request for	AMIN.
			Waiver-Nontarget Insect Testing	
	XVI	154A-24	Request for Waiver—Honey Bee Test	

An intraperitoneal study in the mouse is currently in progress and the results of this study will be submitted to EPA for review in July 1991.

Please do not hesitate to contact me if you have any questions about the submittal package or any other issues related to the registration of GUSANO.

Sincerely yours,

Christine A. Dively

Christine A. Dively Jellinek, Schwartz, Connolly & Freshman, Inc. Authorized Representative of Espro, Inc.

CAD/kjh Enclosures \*Commercial/financial information may be entitled to confidential treatment\*

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8980 Oakland Center Route 108 Columbia, MD 21045 801-596-5811

June 6, 1991

Mr. Donald Stubbs
Acting Branch Chief
Registration Support Branch
Registration Division (H7505C)
United States Environmental Protection Agency
Crystal Mall Bldg. #2; Mail-Stop H-7505C
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Subject: Tolerance Petition Fee Exemption

Dear Mr. Stubbs:

Jellinek, Schwartz, Connolly & Freshman, Inc., will be submitting to you a new product registration application for ACal on our behalf.

We respectfully petition the EPA to exempt Espro, Inc., from the tolerance petition fee because:

- Registration of ACal is in the public interest because it would provide a naturally-occuring biological alternative to chemical pesticides for several insect pests.
- 2. Espro, Inc., is a small company (see the attached March, 1991, unaudited financial statements) for which the fee represents an unreasonable financial burden.

Thank you for considering our request.

Yours/tx

Aldis E. Adamson Vice President

AEA/pt

cc: 1. Mr. Phil Hutton, PM-18

2. Headquarters Accounting Operations Branch

Enclosure

# PLEASE RETURN TO TOLERANCE PETITION DESIROOM 254

## 1015 15th Street, N.W., Suite 500 Washington, D.C. 20005

### JELLINEK, SCHWARTZ, CONNOLLY & FRESHMAN, INC.

Telephone (202) 789-8181 Fax (202) 789-8243 / 789-8244

May 31, 1991

Mr. Phillip O. Hutton
Product Manager (18)
Insecticide-Rodenticide Branch
Registration Division (H7505C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: New Product Registration Application for GUSANO EPA File Symbol 58971-

#### Dear Phil:

On behalf of Espro, Inc. (8980 Oakland Center, Route 108, Columbia, Maryland 21045), I am respectfully submitting an application for pesticide registration and other information to support the registration of GUSANO (Autographa Californica multicapsid nuclear polyhedrosis virus). The following materials are included in the submittal package:

Section	Volume	Guideline #	Study Title
	I	NA	Administrative Materials
A	IIA	151A-10 through 151A-15, 151A-17	Product Chemistry
	IIB	151A-16(f)	Waiver
	IIC	151A-16(g)	Wai <b>v</b> er
В	I	N/A	Label (in Administrative Materials)

Section	Volume	Guideline #	Study Title
С	III	152A-10	Request for Waiver-Acute Oral Toxicity/Pathogenicity
	IV	152A-11	Request for Waiver- Acute Dermal Toxicity
	v	152A-12	Request for Waiver—Acute Pulmonary Toxicity/ Pathogenicity
	VI	152A-14	Request for Waiver—Primary Eye Irritation
	VII	152A-15	Request for Waiver—Hypersensitivity Incidents
	VIII	152A-16	Request for Waiver—Cell Culture
	IX		Request for Waiver-Tier II, Tier III Toxicity Studies
	Х	154A-16	Request for Waiver—Avian Oral Toxicity
	XI	154A-19	Request for Waiver-Freshwater Fish Test
	XII	154A-20	Request for Waiver-Freshwater Aquatic Invertebrate Test
	XIII	154A-21	Request for Waiver-Estuarine and Marine Animal Tests
	XIV	154A-22	Request for Waiver-Nontarget Plant Studies

Section Volume	Guideline #	Study Title
XV	154A-23	Request for Waiver-Nontarget Insect Testing
XVI	154A-24	Request for Waiver-Honey Bee Test

An intraperitoneal study in the mouse is currently in progress and the results of this study will be submitted to EPA for review in July 1991.

Please do not hesitate to contact me if you have any questions about the submittal package or any other issues related to the registration of GUSANO.

Sincerely yours,

Christine A. Dively

Jellinek, Schwartz, Connolly

Christine A. Dively

& Freshman, Inc.

Authorized Representative of

Espro, Inc.

CAD/kjh Enclosures

#### Page 1 of 6

#### Draft Labelling


	GUSANO
ĺ	A Wettable Powder
	Biological Insecticide
	for Control of
1	Caterpillars

GUSANO is an TVP (Insecticidal Virus Product) for control of the caterpillars of the insects listed on this label. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

#### KEEP OUT OF THE REACH OF CHILDREN

CAUTION: See additional precautionary statements and statements of practical treatment on the side panel.

Active Ingredient\*

Polyhedral inclusion bodies (PIBs) of the alfalfa looper nuclear polyhedrosis virus

3.5%

Inert Ingredients:

96.5%

\*This lot contains at least 10 billion PIBs and 1 million activity units (AUs) per gram.

NOTICE: Espro, Inc., makes no warranty, express or implied including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

Mfg. By: Espro, Inc.
8980 Oakland Center EPA REGISTRATION No.:
Route 108 ESTABLISHMENT No.: 53971-HD-001
Columbia, MD 21045

Net Weight: Lot No.:

#### Draft Labelling

# PRECAUTIONARY STATEMENTS C A U T I O N

Hazards to Humans: This product can cause eye irritation. Avoid contact with skin and eyes. Wash thoroughly with soap and water after handling. Call a physician if eye irritation persists.

Do not contaminate water by cleaning of equipment or disposal of wastes.

#### STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Flush eyes with plenty of water. Get medical attention if

irritation persists.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if

irritation persists.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Refer to Technical Bulletin for Additional Guidlines for Use.

GUSANO is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding on foliage. Apply before extensive foliar damage has occurred. When insect infestations are heavy use the higher label rates.

Thorough spray coverage is essential for good insect control. GUSANO should be applied by conventional application equipment with quantities of water to provide thorough coverage of infested plants without runoff.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultraviolet screen is used, add prior to the addition of GUSANO. Mixing time can be reduced by premixing GUSANO with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

#### APPLICATION RATE

Apply 10-50 Million AU's (10-50 grams) of GUSANO per acre treated.

USE NON-CHLORINATED WATER AT A PH NEAR 7.0 IN THE SPRAY-TANK MIX

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#### Page 3 of 6

#### Draft Labelling

#### LABELLED INSECT PESTS

alfalfa looper, beet armyworm, black cutworm, bollworm, cabbage looper, celery looper, corn earworm, cotton leafperforator, diamondback moth, douglas fir tussock moth, eastern tent caterpillar, elm spanworm, europeán corn borer, fall armyworm, fall cankerworm, fall webworm, imported cabbageworm, orangestriped oakworm, pink bollworm, saltmarsh caterpillar, southwestern corn borer, soybean looper, tobacco budworm, tomato fruitworm, white cutworm

#### LABELLED CROPS

#### Vegetables

Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet-corn, peas, asparagus, beets, cauliflower, cucumber, brocolli, onion

#### Other Crops

Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets

#### Silvaculture

Trees of various species

#### RE-ENTRY

GUSANO may be applied up to and including the day of harvest and storage.

#### Page 4 of 6

#### Draft Labelling

#### Storage and Disposal

Bioactivity may be impaired by storage above 90° Fahrenheit. Storing the product in a freezer or refrigerator will extend its shelf-life.

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.

Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with federal and local regulations. Containers should be triple-rinsed and disposed of in an approved landfill or incinerated. Consult Federal, State or local disposal authorities for approved procedures.

#### Page 5 of 6

#### Draft Labelling

# TECHNICAL BULLETIN GUSANO BIOLOGICAL INSECTICIDE

#### PRODUCT DESCRIPTION

GUSANO, produced in the laboratories of Espro, Inc., is an IVP (Insecticidal Virus Product) used to control caterpillars of labelled insect pests.

GUSANO provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

GUSANO is a technical grade lyophilized powder. Its active ingredient is the multicapsid nuclear polyhedrosis virus of the alfalfa looper, Autographa californica.

Active Ingredient\*

Polyhedral inclusion bodies (PIBs) of the alfalfa looper nuclear polyhedrosis virus

3.5%

Inert Ingredients:

96.5%

\*This lot contains at least 10 billion PIBs and 1 million activity units (AUs) per gram.

#### BIOLOGICAL PROPERTIES

GUSANO belongs to the classification Baculovirus, subgroup A. Numerous infectious virus particles or virions are randomly occluded within a protein crystalline matrix called a polyhedral inclusion body (PIB). The average diameter of a PIB is one micron. The virions occluded within the PIBs are the infectious units. Virions are rod-shaped, elongated particles with parallel sides and rounded ends. The virion particle contains viral DNA, which is helically coiled and is enclosed by a lipoprotein envelope.

The product is rapidly inactivated by temperatures above  $90^{\circ}$  F. For prolonged storage, the product should be kept below  $40^{\circ}$  F.

#### Draft Labelling

# TECHNICAL BULLETIN GUSANO BIOLOGICAL INSECTICIDE

#### MODE OF ACTION

The IVP must be ingested to be infective. At early stages of larval development, infection ultimately results in death. The PIBs after ingestion, dissolve within seconds in the midgut. The released infectious virions pass through the epithelial cells lining the midgut, into the cytoplasm and nuclei of susceptible cells. Virtually all the cells of tissues are susceptible.

Assembly of virions and formation of PIBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter.

Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of PIBs.

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST POLYHEDRA TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. GUSANO does not reproduce in mammalian cells or cause them to produce antibodies. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Espro, Inc. and is to be used at the risk of the user of such information.

Espro, Inc. 8980 Oakland Center Route 108 Columbia, MD 21045

